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In The

Supreme Court of the United States

October Term, 1989

MR. AND MRS. FLOYD BROCK, INDIVIDUALLY AND AS NEXT FRIEND OF RACHEL BROCK,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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QUESTION PRESENTED[1]

May a federal court of appeals, in order to provide drug manufacturers with greater predictability, explicitly reject the "traditional role of the jury" in evaluating the credibility of expert witnesses and effectively establish a substantive rule of federal common law requiring "statistically significant epidemiological proof" of causation in "mass toxic tort" cases?

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[1] The parties to this proceeding are identified in the caption of the case.

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MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Petitioners, Mr. and Mrs. Floyd Brock, individually and as next friend of Rachel Brock, request that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Fifth Circuit in the above entitled case.

OPINIONS BELOW

The original opinion and judgment of the three-judge panel of the Court of Appeals for the Fifth Circuit is reported at 874 F.2d 307 and may be found at App. 1. The

panel's opinion modifying its original opinion is reported at 884 F.2d 166 and may be found at App. 21. The order of the Fifth Circuit denying the suggestion for rehearing en banc, and the opinions of the judges dissenting from the denial of rehearing en banc, are reported at 884 F.2d 167 and may be found at App. 23. The decision of the United States District Court is not reported and may be found at App. 32.

JURISDICTION

The original judgment and opinion of the United States Court of Appeals was entered on June 6, 1989. A timely petition for rehearing resulted in the opinion being modified on August 15, 1989. A timely petition for rehearing en banc was denied, with six judges dissenting, on September 8, 1989, and the final timely petition for rehearing from the modified opinion and judgment was denied by an order of the panel entered on September 21, 1989. App. 30. By an order signed by Associate Justice Byron R. White, the time for filing the petition for writ of certiorari was extended to and including January 19, 1990.

This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1). The jurisdiction of the United States District Court was properly invoked pursuant to 28 U.S.C. § 1332.

CONSTITUTIONAL PROVISIONS AND RULE INVOLVED

The Seventh Amendment to the United States Constitution provides,

> "In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court in the United States, than according to the rules of the common law."

The Tenth Amendment to the United States Constitution provides,

> "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

Rule 50(b) of the Federal Rules of Civil Procedure provides, in pertinent part,

> "Whenever a motion for directed verdict made at the close of all the evidence is denied or for any reason is not granted, the court is deemed to have submitted the action to the jury subject to a later determination of the legal questions raised by the motion. . . ."

STATEMENT OF THE CASE

This is a products liability case governed by Texas substantive law. Petitioners Mr. and Mrs. Floyd Brock are the parents of Rachel Brock, who was born on March 19, 1982 with a deformity of the limbs known as Poland's Syndrome. Mrs. Brock had conceived Rachel on or around July 2, 1981. Shortly after she conceived Rachel,

she began to experience morning sickness and, on July 28, 1981, she began taking a prescription drug called Bendectin to control her nausea. The Bendectin taken by Mrs. Brock was manufactured by respondent Merrell Dow Pharmaceuticals, Inc. ("Merrell").

On October 3, 1983, Mr. and Mrs. Brock filed a complaint against Merrell in federal district court in Texas, contending that Rachel's birth defects were caused by her exposure to the Bendectin that had been taken by her mother during pregnancy. They claimed that Merrell was negligent in designing and marketing Bendectin, that the drug was defective and unreasonably dangerous, and that Merrell was liable for Rachel's injuries under theories of negligence and strict liability. The Brocks claimed entitlement to compensatory and punitive damages under Texas law.

At trial, the Brocks supported their allegation that Rachel's exposure *in utero* to Bendectin caused her birth defects with expert testimony from six highly qualified medical doctors and scientists, including three pharmacologists, an obstetrician, an embryologist, and a molecular biologist. Each testified that Bendectin was a teratogen (a substance that causes birth defects) and was capable of causing the particular type of birth defects sustained by Rachel Brock. Their opinions were based in part upon *in vitro* experiments and animal studies showing that Bendectin interferes with embryonic limb growth. The Brocks also called as an expert witness an epidemiologist who testified that, based on his review of population studies published in the medical literature, Bendectin is a teratogen. Three of the Brocks' expert

witnesses – an obstetrician, an embryologist, and a pharmacologist – testified that Bendectin was more likely than not the cause of Rachel's limb deformities. Merrell, of course, disputed the Brocks' allegation that Bendectin caused Rachel's injuries, and presented its own evidence that Bendectin was not a proven teratogen.

The jury returned a verdict favorable to the Brocks, finding that Bendectin had caused Rachel's injuries and awarding the Brocks compensatory and punitive damages. The district court entered judgment based on the jury verdict. Merrell then filed a motion for judgment notwithstanding the verdict under Rule 50 of the Federal Rules of Civil Procedure, asserting that the evidence introduced at trial was legally insufficient to support the jury's finding that Bendectin had caused Rachel's birth defects. The district court, citing "numerous hours of expert testimony," found "ample evidence to sustain the causation findings of the jury," and denied the motion. App. 33.

A three-judge panel of the United States Court of Appeals for the Fifth Circuit, however, reversed the judgment and rendered judgment for Merrell, holding that, as a matter of law, the evidence was insufficient to establish that Bendectin was the cause of the injuries. The court acknowledged that, in its role as reviewing court and not factfinder, it traditionally was not permitted "to weigh the evidence, pass on the credibility of witnesses, or substitute its judgment of the facts for that of the jury." App. 3-4. The court was troubled, though, that the jury in this case was called upon to decide an issue (the teratogenicity of Bendectin) upon which there was no medical consensus and "upon which our brightest medical

minds disagree." App. 6. The court recognized that the traditional approach of leaving disputed questions of science to juries often results in the questions being answered differently in different cases, and felt that this approach fosters "uncertainty among manufacturers contemplating the research and development of new, and potentially life-saving drugs." App. 7-8. Such uncertainty, the court continued, "tend[s] to produce a sub-optimal amount of new drug development." App. 8. Believing this result to be undesirable, that "cases such as this present special problems and challenges to traditional ideas regarding the role of the jury as a decisionmaker," App. 5, and that appellate courts should "take the lead in resolving those questions upon which juries will go both ways," App. 8, the court proceeded to evaluate the persuasiveness of the Brocks' evidence.

The court held that the record reflected a lack of "conclusive epidemiological proof" (App. 16) that Bendectin was capable of causing limb reduction defects, and that this lack of proof was fatal to the Brocks' contention that their daughter's injuries were caused by Bendectin. The court arrived at this result while admitting that the Brocks had presented one study, characterized by the Brocks' expert as significant, showing that among children exposed to Bendectin, the incidence of limb reduction defects like Rachel's was increased by forty-nine percent over that among children that had not been exposed. App. 14. On the Brocks' petition for rehearing, the Fifth Circuit panel revised its opinion to state that the absence of "statistically significant epidemiological proof" was fatal to the Brocks' claim. App. 21-22.

The Fifth Circuit denied rehearing en banc. In a dissent joined by six of the fourteen judges, Judge Reavley pointed out that "[s]ix highly qualified and experienced experts testified that bendectin is a human teratogen," and that "[t]hree of them testified to the opinion that bendectin was a cause of Rachel Brock's deformation." App. 24. These opinions, he noted, "were not the product of faulty syllogisms but were predicated upon medical study and research." App. 24. The court's characterization of such proof as speculation, Judge Reavley observed, "could just as well doom virtually all expert testimony." App. 24. Judge Reavley criticized the court for debating the statistical significance of the Brocks' epidemiological proof, and disputed the court's "novel declaration that only epidemiological studies can prove causal relation between Bendectin and birth defects." App. 24. He also condemned on policy grounds the court's holding that convincing epidemiological proof was required to support the Brocks' allegation of causation, noting that "no epidemiological study has ever discovered a teratogen." App. 25. Fearing that other courts would adopt the approach of the court in this case, Judge Reavley "wonder[ed] what is left in this circuit of the *Boeing* rule or, for that matter, the Seventh Amendment right to trial by jury." App. 24.[2]

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[2] The "*Boeing* rule," was announced in *Boeing Co. v. Shipman*, 411 F.2d 365 (5th Cir. 1969)(en banc), and set forth the standard for evaluating the legal sufficiency of the evidence to support a jury finding. The court in *Boeing* held that "it is the function of the jury as the traditional finder of the facts, and not the Court, to weigh conflicting evidence and inferences, and determine the credibility of witnesses." 411 F.2d at 375.

REASONS FOR GRANTING THE WRIT

I. THE MISAPPLICATION OF RULE 50 OF THE FEDERAL RULES OF CIVIL PROCEDURE BY THE COURT OF APPEALS IN REVERSING A JUDGMENT SUPPORTED BY PROPERLY ADMITTED EXPERT OPINION EVIDENCE IS AN ERROR OF CONSTITUTIONAL DIMENSION, AND CALLS FOR SUPERVISORY REVIEW BY THIS COURT.

Rule 50 of the Federal Rules of Civil Procedure empowers a trial or appellate court to disregard a jury's verdict and to enter judgment for the verdict-loser only if the evidence "is so one-sided that [the moving party] must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). Neither Rule 50 nor the Seventh Amendment permits the reviewing court to determine which side's case is more persuasive; that task is left, by constitutional imperative, for the jury. The reviewing court is permitted to inspect the factual record only to determine whether the evidence, viewed in the light most favorable to the verdict-winner, would allow a reasonable jury to return the verdict actually rendered.

In the instant case, the Brocks presented six expert medical witnesses who testified that the Bendectin manufactured by Merrell was capable of causing birth defects of the type experienced by Rachel Brock. Three of these expert witnesses testified unequivocally that the Bendectin taken by Mrs. Brock during her pregnancy was the probable cause of Rachel Brock's birth defects. The admissibility of this expert testimony was not questioned by the appellate court. Rather, the court of appeals simply ruled that the expert opinions that Bendectin caused Rachel Brock's birth defects were not persuasive enough

to allow a reasonable jury to find the causal relationship alleged. By applying Rule 50 in this manner, the court of appeals usurped the role of the jury and the district court, and deprived the Brocks of their constitutional right to a jury determination of contested factual issues.

In its opinion, the court of appeals admitted that the Brocks did present evidence that Bendectin caused Rachel Brock's birth defects, in the form of the ultimate opinions of the three experts. The court then noted its obligation to inspect the foundation upon which these ultimate opinions were based, in order to determine whether a reasonable jury would credit them. But the court did more than merely determine whether the expert opinion evidence offered in support of the Brocks' claim had a colorable scientific basis; it evaluated the weight of the evidence that the Brocks produced. For example, the Brocks produced evidence that limb reduction defects occurred forty-nine percent more frequently in populations exposed *in utero* to Bendectin than in populations not so exposed. App. 14. The Brocks' proof lacked statistical significance, the court held, because it failed to satisfy a "confidence interval" of 1.0 or greater. App. 13-14. A study that meets this "confidence interval" has a ninety-five percent likelihood of being accurate;[3] studies that do not are not as certain to be accurate, but are still, at the very least, sufficient to prove that causation is more likely than not. Yet the court discounted the Brocks' epidemiological proof entirely. Similarly, the court acknowledged that experiments on laboratory animals tended to show

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[3] See trial transcript at 977-82 (testimony of Merrell's epidemiologist, Dr. Steven Lamm, explaining the concept of confidence intervals).

that Bendectin could cause limb reduction defects similar to the type sustained by Rachel Brock, but stressed the "very limited usefulness of animal studies" on questions of toxicity. App. 16. The court ultimately concluded that the absence of "statistically significant epidemiological proof" of a causal link between Bendectin and the type of damage sustained by Rachel Brock was fatal, as a matter of law, to the Brocks' case.

The court thus did precisely what it acknowledged at the beginning of the opinion it could not do: it judged the persuasiveness of the Brocks' scientific evidence and substituted its own judgment of the facts for that of the jury. The court's departure from the traditional standard for reviewing the legal sufficiency of the evidence is explained by its perception that cases involving injuries allegedly caused by toxic substances "present special problems and challenges to traditional ideas regarding the role of the jury as a decisionmaker." App. 5. The court's lack of faith in the jury system to resolve questions of causation in toxic tort cases, however, does not justify ignoring the limitation of its function as factfinder under Rule 50 and the Seventh Amendment. As this Court has observed,

> It is the jury, not the court, which is the fact-finding body. It weighs the contradictory evidence and inferences, judges the credibility of the witnesses, receives expert instructions, and draws the ultimate conclusion as to the facts. The very essence of its function is to select from among conflicting inferences and conclusions that it considers most reasonable. That conclusion, whether it relates to negligence, causation or any other factual matter, cannot be ignored. Courts are not free to reweigh the evidence and

> set aside the jury verdict merely because the jury could have drawn different inferences or conclusions or because judges feel that other results are more reasonable.

Tennant v. Peoria & Pekin Union Ry., 321 U.S. 29, 35 (1944) (citation omitted).

In the instant case, the appellate court rejected not only the finding of the jury but also the ruling of the trial judge that the evidence on causation was sufficient to create a jury issue. After listening to "numerous hours of testimony," App. 33, and observing the demeanor of the witnesses who gave that testimony, the trial judge determined that the Brock's evidence would allow a reasonable jury to find that Rachel Brock's exposure *in utero* to Bendectin caused her deformity. As one esteemed constitutional scholar rhetorically asked, "is there any reason to suppose that the result an appellate court reaches [on issues of fact] is more likely to be 'just' than was the opposite result reached by the trial court?" Wright, *The Doubtful Omniscience of Our Appellate Courts*, 41 Minn.L.Rev. 751, 781 (1957). Professor Wright answered that an appellate court's factual findings are probably less reliable than those of the trial court, because the trial judge "has the vast advantage of having lived with the case and heard the witnesses," while the appellate court "has lawyers before it picking out bits and pieces of the record to attack or defend a particular finding." *Id.* at 781-82. Professor Wright's observations have particular relevance in this case, in which, as Judge Reavley's dissent points out, the court "pick[ed] at details in the testimony" rather than simply determining whether a colorable factual issue was presented. App. 24.

The court of appeals suggested that another circuit has similarly applied Rule 50 to invalidate a jury finding of causation in a Bendectin case, citing *Richardson by Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C.Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989). But as Judge Reavley noted in his dissent from the denial of rehearing en banc, App. 25, *Richardson* involved an interpretation of the Federal Rules of Evidence, not the application of the rules governing when it is procedurally and constitutionally permissible to take a case from the jury. In *Richardson*, the trial court ruled that the testimony of plaintiffs' principal witness that Bendectin had caused the birth defect was inadmissible under Rule 703 of the Federal Rules of Evidence, and found no other evidence to support plaintiffs' allegation of causation. 857 F.2d at 827. It thus granted judgment notwithstanding the verdict. *Id.* The court of appeals affirmed, noting that "the admissibility of testimony . . . is the crux of our decision in this case." *Id.* at 825 n.9.

In contrast, the admissibility of the expert opinion evidence relied upon by the Brocks in the instant case was questioned neither by the trial court nor by the court of appeals. The suggestion that *Richardson* dictates, or even supports, the result reached by the court below is thus more than merely mistaken; it is dangerous. It assumes that the standard for *affirming* a district court's discretionary exclusion of evidence is the same as the standard for *reversing* a district court's refusal to disturb a jury verdict supported by properly admitted evidence. When the credentials of an expert are assailed, and the

foundation of his opinion undercut, so that as in *Richardson* the trial judge rules that the testimony is inadmissible,[4] and no other evidence supports the verdict, the application of Rule 50 may well be proper. But when the expert testimony is not excluded, and even the appellate court does not question its admissibility, as in the instant case, then it is inconceivable that a court could interfere with jury verdict without impermissibly weighing the evidence itself. The court's unprecedented relaxation of the standard for reviewing jury decisions is inconsistent with the strict standard of such review heretofore applied by the federal courts, and demands examination by this Court.

The Brocks acknowledge the general rule that the Seventh Amendment does not prevent a trial or appellate court from taking a case from the jury if reasonable minds could not differ as to which party should prevail. As Judge Reavley observed in his dissent, however, the Seventh Amendment's guarantee of trial by jury is implicated when an appellate court passes on the credibility of properly admitted scientific testimony supporting a jury

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[4] The Brocks do not concede that the expert testimony was properly excluded in *Richardson*. On the contrary, an expert opinion need not be supported by epidemiological evidence to be reliable, and cases interpreting the Federal Rules of Evidence have thus routinely held such opinions admissible. *See, e.g., Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741 (11th Cir. 1986), *cert. denied*, 479 U.S. 950 (1986). However, the Brocks submit that the instant case presents an issue different from, and more important than, that presented in *Richardson*: the extent to which a court can substitute its own evaluation of properly admitted expert opinion evidence for that of the jury.

finding. For the court in this case to conclude that reasonable minds could not find that Bendectin caused the injuries of Rachel Brock, it had to analyze and reject properly admitted expert testimony that Bendectin *did* cause the injuries. The interpretation of such evidence is, as the court conceded, "just a matter of opinion." App. 5. If an appellate court, or even a trial court, can evaluate expert testimony and substitute its own resolution of the conflicts in that testimony for that of the jury, the constitutional guarantee of a civil trial by jury is reduced to a nullity in toxic tort cases.

This Court has long recognized that the ability of a trial or appellate court to disregard a jury verdict and enter judgment based on the legal insufficiency of the evidence is limited by the Seventh Amendment. *Atlantic & Gulf Stevedores v. Ellerman Lines*, 369 U.S. 355, 358-59 (1962). *See also Lust v. Clark Equipment Co.*, 792 F.2d 436, 437-38 (4th Cir. 1986); *Abernathy v. Superior Hardwoods, Inc.*, 704 F.2d 963, 971 (7th Cir. 1983). In no other reported case has a federal appellate court reversed a trial court's refusal to disturb a jury verdict based on the appellate court's own dispute with the properly admitted opinions of the prevailing party's expert. The court's decision in this case raises grave and novel questions of exceptional importance about the degree to which a federal court can weigh the facts in diversity cases in general, and toxic tort cases in particular, consistent with Rule 50 and the Seventh Amendment. This Court should therefore invoke its power of supervision to review the decision.

II. THE DECISION OF THE COURT OF APPEALS REQUIRING "STATISTICALLY SIGNIFICANT EPIDEMIOLOGICAL PROOF" TO SUPPORT A JURY FINDING OF CAUSATION IN A TOXIC TORT CASE CONFLICTS WITH HOLDINGS OF OTHER FEDERAL AND STATE APPELLATE COURTS.

The court of appeals conceded that the Brocks' evidence supported an inference that Bendectin caused Rachel Brock's birth defects, but stressed that in order to support the jury finding of causation, the inference had to be reasonable. It concluded that the inference of causation could not survive the absence of persuasive epidemiological proof of a causal relation between Bendectin and birth defects. The court's holding that the inference of causation was unreasonable in this case suggests that any inference that a particular chemical caused a particular injury not supported by convincing epidemiological evidence is inherently unreasonable.

Yet other federal circuit courts of appeals, as well as other state appellate courts, have recognized that legal determinations of causation can be made without the type of epidemiological evidence that is considered indispensable by the Fifth Circuit. For example, in *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741 (11th Cir. 1986), *cert. denied*, 479 U.S. 950 (1986), the Eleventh Circuit Court of Appeals expressly rejected a spermicide manufacturer's contention that a finding that its product had caused plaintiff's birth defects could not be upheld without epidemiological evidence of a "statistically significant" association between spermicides and birth defects. 788 F.2d at 745. The court recognized the distinction between the degree of proof necessary to establish a

scientific consensus and the degree of proof necessary to support civil liability, observing,

> If the factfinder here is convinced that plaintiffs have proven to a reasonable degree of medical certainty, which is the legal standard employed in this case, that Ortho-Gynol caused Katie Wells' arm, shoulder and hand defects, it does not matter in terms of deciding the case that the medical community might require more research and evidence before conclusively resolving the question. What matters is that this particular factfinder found sufficient evidence of causation in a legal sense in this particular case, and that that finding is not clearly erroneous.

Id. The language and holding in *Wells* irreconcilably conflicts with the result and rationale in the instant case.

Other appellate courts, federal and state, have ruled that a reasonable finding of a causal relationship between a toxic substance and physical harm need not be predicated on epidemiological evidence. *See, e.g., City of Greenville v. W.R. Grace & Co.*, 827 F.2d 975, 980 n.2 (4th Cir. 1987); *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1536 (D.C.Cir. 1984), *cert. denied*, 469 U.S. 1062 (1984); *Earl v. Cryovac, A Div. of W.R. Grace Co.*, 115 Idaho 1087, 772 P.2d 725, 733 (Idaho Ct.App. 1989); *Baroldy v. Ortho Pharmaceutical Corp.*, 157 Ariz. 574, 760 P.2d 574, 582 (Ariz.Ct.App. 1988). Thus, the holding in the instant case not only conflicts with other federal and state decisions, but also reflects an aberrational view on the issue.

If a federal rule for determining the sufficiency of the evidence of causation in a toxic tort case is to be applied,[5] that rule should be consistently applied in all the circuits. The rule applied in the instant case conflicts with the rule applied in *Wells, Ferebee, City of Greenville,* and by various state appellate courts. This Court should review the decision of the court of appeals in order to resolve the conflict.

III. BY EXPRESSLY REALLOCATING THE BURDEN OF PROOF IN TOXIC TORT CASES, WITHOUT ANY SUPPORT IN THE JURISPRUDENCE OF THE STATE WHOSE LAW IT WAS BOUND TO APPLY, THE COURT OF APPEALS VIOLATED FUNDAMENTAL PRINCIPLES OF FEDERALISM, REQUIRING CORRECTIVE ACTION BY THIS COURT.

This Court has long recognized that in a diversity case, the burden of proof that a litigant must carry in order to support a jury verdict is a question of state substantive law. *Cities Services Oil Co. v. Dunlap,* 308 U.S. 208, 211 (1939); *see also Guaranty Trust Co. v. York,* 320 U.S. 99, 109 (1945). Texas products liability law, which governs this case, requires a plaintiff to prove that the defendant's defective product was a producing cause of his injuries "by a preponderance of the evidence" in order to recover. State Bar of Texas, *Texas Pattern Jury Charges,* Vol.3, § 30.04 (1982) at 12. This rule of substantive law requires

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[5] The Brocks oppose creation and application of such a federal rule, because the type and degree of proof necessary to support a cause of action is, and constitutionally must be, a matter of state law. See Part III of this petition.

that the plaintiff show that it is more likely than not that the defendant's defective product contributed to the plaintiff's injury. *Id.*

In accordance with Texas law, the district court instructed the jury that the plaintiffs below bore the burden of establishing the causal relationship between the Bendectin ingested by Mrs. Brock and the injuries sustained by Rachel Brock "by a preponderance of the evidence." Trial transcript at 1434. Later, in denying defendant's motions attacking the jury's finding of causation, the district court properly noted that plaintiffs' evidence need only satisfy the "more probable than not standard." App. 33.

In reviewing the district court's orders upholding the jury's verdict, however, the court of appeals applied a different burden of proof. The court observed that in pharmaceutical products liability cases such as the instant case, in which there is no scientific consensus on the ability of the product to cause the injury, "juries often split both ways on the issue," causing "uncertainty among manufacturers contemplating the research of new, and potentially lifesaving drugs." App. 7-8. The court deemed this state of affairs to be undesirable as a matter of public policy, and sought to fashion an approach which would "reduce some of the uncertainty which can tend to produce a sub-optimal amount of new drug development." App. 8. To achieve this result, it held that in order for the jury's finding on causation in this case to be sustained, the causal relationship between Bendectin and Rachel Brock's precise injury must be established by "statistically significant epidemiological proof." App. 22. This rule required the Brocks to prove the association between

Bendectin and limb reduction defects to a degree of likelihood of at least ninety-five percent, rather than simply by a preponderance of the evidence.[6]

The court thus chose to create a new federal law of proving causation in toxic tort cases, rather than to apply the traditional burden of proof required by Texas substantive law. Nothing in Texas law supports the court's conclusion that in a toxic tort case, a plaintiff must present statistically significant epidemiological proof suggesting that the injury was caused by the toxic substance in order to recover. On the contrary, the rule that a plaintiff must prove his allegations "by a preponderance of the evidence" obtains regardless of the complexity of the proof of causation. Texas courts have not crafted a different standard of proof to be applied in products liability cases involving toxic substances or prescription drugs, nor have they even intimated that a more demanding standard will or should be applied in such cases. *See, e.g., Farm Services, Inc. v. Gonzales*, 756 S.W. 747, 750-51 (Tex.Ct.App. 1988) (lay testimony of plaintiff alone sufficient to establish that exposure to toxic chemical was a producing cause of his injury, despite expert opinions to the contrary introduced by defendant); *see also Morgan v. Compugraphic Corp.*, 675 S.W.2d 729 (Tex. 1984) (plaintiff's lay testimony on medical causation, if reliable, satisfies burden of production). Under Texas law, *any* evidence, whether elicited from lay witnesses or from experts, establishing that it is more likely than not that the toxic agent was a producing cause of the harm, is sufficient to support a finding of causation in a toxic tort case. The

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[6] See footnote 3, *infra*.

court of appeals thus held the Brocks to a greater burden of proving causation than that applicable under Texas substantive law.

Both this Court and the federal appellate courts have consistently rejected efforts to create a federal common law of products liability, wisely noting that this area of the law must remain in the domain of the state courts. Most recently, in *Browning-Ferris Industries v. Kelco Disposal, Inc.*, 109 S.Ct. 2909 (1989), this Court declined the invitation to craft a common law standard of excessiveness of punitive damages verdicts, stating that "these are matters of state, and not federal, common law. Adopting a rule along the lines petitioners suggest would require us to ignore the distinction between state law and federal law issues." *Id.*, 109 S.Ct. at 2921. The Fifth Circuit previously has refused to develop a federal common law governing the availability of punitive damages in asbestos litigation, reasoning that "in a diversity action federal court concerns in a just judicial system cannot be used as a reason for supplanting substantive state policies." *Jackson v. Johns-Manville Sales Corp.*, 750 F.2d 1314, 1326 (5th Cir. 1985) (en banc), *cert. denied*, 478 U.S. 1022 (1986).

Strict products liability, the substantive law of this case, is a compelling example of the necessity for federal courts to avoid creating a federal common law of torts that undermines state policy. Strict liability essentially lowered the burden of proof demanded of injured victims of defective products. A scholar who was instrumental in shaping this doctrine explains that strict liability was a considered attempt to advance various specific notions of justice and social policy: to relieve injured victims of the unfair and often impossible burden of proving negligent

conduct by a remote manufacturer, to further public safety by providing a stronger deterrent to the marketing of unsafe products, and to impose the cost of injury upon those who are best able to spread the risk or insure against it. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss.L.J. 825, 826 (1973). These policy interests are recognized in Texas. *Duncan v. Cessna Aircraft Co.*, 665 S.W.2d 414 (Tex. 1984).

But by applying unduly high standards for proving causation in scientifically difficult cases such as the case at bar, the federal courts risk undermining the very purpose for which the state adopted strict liability. Indeed, the policy interest that the court of appeals explicitly sought to promote by its decision in this case, the unrestrained development of new pharmaceuticals (App. 8), has never been recognized by the Texas courts. Additionally, such a rule invites defendants in products liability cases to remove to federal court whenever possible, a result that *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938) expressly sought to prevent. If the court's approach in the instant case prevails, the federal courts will increasingly be placed in the anomalous position of developing state tort law in precisely those difficult cases, characterized by competing interests and policies, which should be the responsibility of state courts.

The rule established by the court below threatens the delicate balance of our system of federalism. It represents an unwarranted intrusion by the court into an area of substantive law reserved to the states by the Tenth Amendment and by *Erie* and its progeny. Supreme Court review is essential because the court of appeals, by

requiring epidemiological support for findings of causation in all toxic tort cases, has erected a new, federal rule of law for cases that have always been governed by the substantive law of the states.

CONCLUSION

The judgment of the court of appeals is the result of an unprecedented, ill-advised, and alarming exercise in appellate fact-finding, an exercise that is not contemplated by Rule 50 and is prohibited by the Seventh Amendment. The decision fails to apply the Texas rules concerning the burden of proof, and instead develops a presumption of substantive law that has no support in Texas jurisprudence, thus doing violence to principles of federalism recognized by this Court since *Erie*. For these reasons, the Brocks respectfully pray that this Court issue

a writ of certiorari to review the decision of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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APPENDIX

Mr. and Mrs. Floyd BROCK, individually and as next friend of Rachel Brock, a minor, Plaintiffs-Appellees,

v.

MERRELL DOW PHARMACEUTICALS, INC., Defendant-Appellant.

No. 88-2311.

United States Court of Appeals, Fifth Circuit.

June 6, 1989.

O.J. Weber, Mehaffey, Weber, Keigh & Gonsoulin, Beaumont, Tex., Robert M. Dato, Santa Monica, Cal., Ramey, Flock, Hutchins, Jeffus, McClendon & Crawford, P.C., Tyler, Tex., for defendant-appellant.

Thomas H. Bleakley, Detroit, Mich., W. James Kronzer, Richard Warren Mithoff, Houston, Tex., for plaintiffs-appellees.

Appeal from the United States District Court for the Eastern District of Texas.

Before GARZA, JOLLY, and JONES, Circuit Judges.

GARZA, Circuit Judge:

Mr. & Mrs. Floyd Brock filed suit in federal district court on behalf of their minor child, Rachel Brock, to recover damages for birth defects that allegedly resulted from Mrs. Brock's ingestion during her pregnancy of the anti-nausea drug Bendectin, which is manufactured by Merrell-Dow Pharmaceuticals, Inc. ("Merrell-Dow"). The Brocks obtained a jury verdict in the amount of $550,000 against Merrell-Dow, representing $240,000 in compensatory damages and $310,000 in punitive damages. Merrell-

Dow appeals that verdict here, arguing that the Brocks did not present sufficient evidence to allow the jury to conclude that Bendectin caused Rachel Brock's birth defect. After reviewing the record and decisions of other courts confronted with similar suits regarding Bendectin, we hold that Merrell-Dow was entitled to judgment notwithstanding the verdict, and the judgment in favor of the Brocks is therefore reversed and the case will be dismissed.

Background

Mrs. Brock conceived Rachel Brock on or around July 2, 1981. On July 28, 1981, Mrs. Brock began to experience morning sickness, and she began to take Bendectin, a prescription drug manufactured by Defendant, Merrell-Dow.[1] Rachel Brock was born on March 19, 1982 with a limb reduction defect known as Poland's Syndrome, which is recognized by a shortening or absence of fingers with a decrease in the corresponding pectoralis muscle on one side.

Mr. and Mrs. Brock filed a diversity suit against Merrell-Dow on behalf of their daughter in the U.S. District Court for the Eastern District of Texas. The complaint alleged theories of improper inspection, design defect, and failure to warn. Causation was a hotly contested issue, with both sides presenting expert testimony

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[1] Bendectin, a trade name, consists of 10 mg. doxylamine succinate and 10 mg. pyridoxin (Vitamin B-6).

and studies regarding the possible teratogenicity[2] of Bendectin. At the end of trial, Merrell-Dow moved for a directed verdict, arguing that there was no credible evidence tending to show that Bendectin causes birth defects. Merrell-Dow's motion was denied, and the issue of whether Bendectin caused Rachel Brock's birth defect was given to the jury. The jury found for the Brocks, and awarded both compensatory and punitive damages. Merrell-Dow then moved for judgment notwithstanding the verdict, and that motion was denied. Merrell-Dow here appeals the denial of its motions for directed verdict and for judgment notwithstanding the verdict.[3]

Standard for Determining Sufficiency of the Evidence

The standard for granting a judgment notwithstanding the verdict is the same as that governing rulings on directed verdicts: judgment notwithstanding the verdict is proper only when there can be only one reasonable conclusion drawn from the evidence. *Dun & Bradstreet, Inc. v. Miller,* 398 F.2d 218, 224 (5th Cir.1968). It is generally accepted that the court, in determining whether the evidence is sufficient to present a question for the jury, is not free to weigh the evidence, pass on the credibility of

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[2] A teratogen is a substance that causes birth defects.

[3] Merrell-Dow raises two other points on appeal, specifically, 1) that a new trial should be ordered because one of plaintiff's experts presented a study that allegedly relied on fraudulent data, and 2) that punitive damages were inappropriate. Our reversal on the grounds that there was insufficient credible evidence that Bendictin (sic) causes birth defects to send this case to the jury obviates the need for us to address these other two points.

witnesses, or substitute its judgment of the facts for that of the jury. *See Glazer v. Glazer*, 374 F.2d 390, 400 (5th Cir.1967), cert. denied 389 U.S. 831, 88 S.Ct. 100, 19 L.Ed.2d 90; *Alman Bros. Farms & Feed Mill, Inc. v. Diamond Lab, Inc.*, 437 F.2d 1295, 1298 (5th Cir.1971); *Cardwell v. U.S.*, 186 F.2d 382 (1951); *see generally* 9 Wright & Miller, Federal Practice and Procedure Sec. 2524 (1971). Viewing the evidence in the light most favorable to the party against whom the motion is made, the court must give that party the benefit of all reasonable inferences from the evidence. *Boeing Co. v. Shipman*, 411 F.2d 365, 375 (1969).

These general and abstract formulations lose much of their usefulness, however, when we attempt to apply them to the concrete factual situation at hand. One certainly might infer from the evidence in the case that Bendectin causes birth defects, and further that Bendectin caused Rachel Brock's limb reduction defect – in fact, the jury concluded that this very thing occurred. However, the court must determine whether this is a *reasonable* inference to be drawn from the evidence presented, and the formulae provide us with little guidance as to what constitutes a reasonable as opposed to unreasonable, inference that a jury could draw from the evidence.[4] Ultimately, the "correctness" of our decision that there was insufficient evidence presented by plaintiff on the

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[4] One commentator notes that "[i]t is commonplace that in large part the problem of defining the range of reasonable inference is dependent on the unique circumstances of each particular case. No self-applying rule can be offered for determining what inferences are reasonable." Cooper, *Directions for Directed Verdicts: A Compass for Federal Courts*, 55 Minn.L.Rev. 903, 956 (1971).

issue of whether Bendectin caused Rachel Brock's limb reduction defect to enable a jury to draw a reasonable inference may be just a matter of opinion, but hopefully the reasoning below will persuade others of the insights of our perspective.

This case is one of a series of many cases filed against Merrell-Dow by parents of children with birth defects allegedly caused by the ingestion of Bendectin during pregnancy. Academic commentators have dubbed this case and other like it "mass toxic torts."[5] This represents a growing realization among academics, lawyers, and judges that cases such as this present special problems and challenges to traditional ideas regarding the role of the jury as a decisionmaker.

The first problem is that there is often no consensus in the medical community regarding whether a given substance is teratogenic; this is the case with Bendectin. Moreover, while we now recognize some of the many factors which can cause birth defects, medical science is now unable, and will undoubtedly remain unable for the foreseeable future, to trace a known birth defect back to its precipitating cause.[6] The second problem, in addition

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[5] *See* Abraham, *Individual Action and Collective Responsibility: the Dilemma of Mass Tort Reform*, 73 Va.L.Rev. 845 (1987); *Black & Lilienfeld, Epidemiologic Proof in Toxic Tort Litigation*, 52 Fordham L.Rev. 732 (1984); Sugarman, *Doing Away with Tort Law*, 73 Calif.L.Rev. 555 (1985).

[6] Advances in science and medical technology have shed new light on the the (sic) way we perceive our world, but in so

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to the problem of unknowability, is that juries are asked to resolve these questions, upon which even our brightest medical minds disagree, in order to resolve the case at hand and decide whether the plaintiff is entitled to recovery, and in so doing must necessarily resort to speculation.

Under the traditional approach to scientific evidence, courts would not peer beneath the reasoning of medical experts to question their reasoning.[7] Confronted, as we

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doing have raised new questions for our legal system. Professor Black notes that:

> [a]round the turn of the twentieth century, however, advances in physiology and psychology and the advent of the quantum and relativity theories destroyed simple, mechanistic certainty. Quantum theory tells us that certainty is a physical impossibility, relativity that time is not absolute, and psychology that preconceptions color supposedly objective accounts of the natural world.

Black *A Unified Theory of Scientific Evidence*, 56 Fordham L.Rev. 595 (1988), *See generally* Kuhn, *The Structure of Scientific Revolutions* 5-7 (critiquing scientific method by noting that "normal science" is based on the assumptions of the commonly accepted paradigms, but a new theory can lead to a change in the accepted paradigms of normal science).

[7] *Pike County Highway Dept v. Fowler*, 180 Ind. App. 438, 388 N.E.2d 630 (1979) (plaintiff who received workers' compensation for a work related injury to his foot, which eventually had to be amputated, presented evidence at trial in the form of testimony by an osteopath that, in his opinion after observations and examinations of plaintiff over the years, plaintiff's circulatory problems were caused by the trauma to

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now are, with difficult medical question, courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them. Moreover, in mass torts the same issue is often presented over and over to juries in different cases, and the juries often split both ways on the issue.[8] The effect of this is to create a state of uncertainty among

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the foot. The court, in allowing this issue to go to the jury even though defendant's expert pointed out that, for the osteopath's reasoning to be correct, an embolism would have had to travel from the foot, through the heart and lungs, and back to the leg, which would have killed the plaintiff, noted that the osteopath had laid out a legally adequate foundation for his opinion.); *Boldt v. Jostens, Inc.*, 261 N.W.2d 92 (Minn.1977) (doctor testifying about plaintiff's lung and kidney disease acknowledged that its etiology was unknown, but nonetheless opined that exposure to glue fumes at defendant's factory had a great deal to do with defendant's illness, and had certainly caused aggravation).

[8] Over a century ago, Holmes identified this problem: But supposing a state of facts is often repeated in practice, is it to be imagined that the court is to go on leaving the standard to the jury forever? Is it not manifest, on the contrary, that if the jury is, on the whole, as fair a tribunal as it is represented to be, the lesson which can be got from that source will be learned? Either the court will find that the fair teaching of experience is that the conduct complained of usually is or is not blameworthy, and therefore, unless explained, is or is not a ground of liability; or it will find the jury oscillating to and fro, and will see the necessity of making up its mind for itself.

O. Holmes, The Common Law 98 (1881).

manufacturers contemplating the research and development of new, and potentially lifesaving drugs.[9] Appellate courts, if they take the lead in resolving those questions upon which juries will go both ways, can reduce some of the uncertainty which can tend to produce a sub-optimal amount of new drug development.

We are not without precedent in our approach to this problem. The case before us parallels in many respects the recently conducted Agent Orange Litigation.[10] In those cases, plaintiffs attempted to prove that exposure to Agent Orange, a defoliant used during the Vietnam War, had caused them adverse health effects. Judge Weinstein granted summary judgment against opt-out plaintiffs on the basis that they had been unable to prove that exposure to low levels of dioxin caused their health problems. Although plaintiffs had provided the affidavits of experts indicating that exposure to Agent Orange had caused

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[9] Merrell-Dow has already taken Bendectin off the market out of fear of liability, even though there is not one study which definitively proves that Bendectin is a teratogen. Doctors are now forced to prescribe less extensively studied drugs, or perhaps nothing at all. The effects of uncertainty regarding liability extend beyond Bendectin. Private companies are withdrawing, not only from marketing but even from developing, birth control technology. Gladwell, *U.S. Firms Abandoning Birth Control Industry in Wake of Lawsuits*, Washington Post, May 1, 1988 at H-1, col. 1.

[10] *In Re Agent Orange Prod. Liab. Litig.*, 597 F.Supp. 740 (E.D.N.Y.1984), aff'd 818 F.2d 145 (2d Cir.1987); *In Re Agent Orange Prod. Liab. Litig.*, 611 F.Supp 1223 (E.D.N.Y.1985).

their health problems, the court attacked the reasoning of the experts and found it to be inadequate.[11]

Courts have not always been so willing to analyze the reasoning employed by experts to reach their conclusions. In *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C.Cir.1984), *cert. denied* 469 U.S. 1062, 105 S.Ct. 545, 83 L.Ed.2d 432 (1984), the District of Columbia Circuit considered the question of whether a fatal lung disease contracted by an agricultural worker was caused by his exposure to paraquat, a defoliant. Plaintiff presented two experts who expressed the opinion that paraquat had caused his illness, even though they admitted that cases like the plaintiff's were rare. The court denied defendant's motion for judgment notwithstanding the verdict, and in so holding, noted that "[j]udges . . . have no

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[11] The court noted that:

> [plaintiff's expert's] testimony amounts to this: the affiants complain of various medical problems; animals and workers exposed to extensive dosages of TCDD have suffered from related difficulties; therefore, *assuming nothing else caused the affiants' afflictions,* Agent Orange caused them. One need hardly be a doctor of medicine to make the statement that if X is a possible cause of Y, and if there is no other possible cause of Y, X must have caused Y. [Plaintiff's expert's] formulation avoids the problem before us: which of myriad [sic] possible causes of Y created a particular veteran's problems. . . . His analysis, in addition to being speculative, is so guarded as to be worthless.

611 F.Supp. at 1237-38 (emphasis added).

special competence to resolve the complex and refractory causal issues raised by the attempt to link low level exposure to toxic chemicals with human disease. On questions such as these, which stand at the frontier of current medical and epidemiological inquiry, if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony." *Id.* at 1534.

The District of Columbia Circuit retreated from this approach recently when it considered, in a Bendectin case, the very same issue we are addressing here. In *Richardson by Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C.Cir. 1988), the D.C. Circuit affirmed the lower court's grant of judgment notwithstanding the verdict to defendant. In its discussion of its approach to resolving the conflicting expert testimony in favor of defendant, the court opined that "[e]xpert witnesses are indispensible (sic) in a case such as this. But that is not to say that the court's hands are inexorably tied, or that it must accept uncritically any sort of opinion espoused by an expert merely because his credentials render him qualified to testify." *Id.* at 829. The court then proceeded to look behind the conclusion of plaintiff's expert and found his reasoning inadequate. In distinguishing *Ferebee*, the court narrowly interpreted the case to apply only where the causation issue is novel and "stands at the frontier of current medical and epidemilogical (sic) inquiry." *Id.* at 832. The Bendectin cases are different, opined the D.C. Circuit, in that there is a wealth of published epidemiological data, none of which has concluded that the drug is teratogenic. Thus, in *Richardson*, the court affirmed its willingness to look behind the conclusions of experts, at

least in cases which are not at the frontier of epidemiological inquiry.[12] We too, have chosen to take the same approach as the *Richardson* court, and in the next section we will present our analysis of the reasoning employed by the expert witnesses in this case.

Sufficiency of the Evidence Presented

Undoubtedly, the most useful and conclusive type of evidence in a case such as this is epidemiological studies. Epidemiology attempts to define a relationship between a disease and a factor suspected of causing it – in this case, ingestion of Bendectin during pregnancy. To define that relationship, the epidemiologist examines the general population, comparing the incidence of the disease among those people exposed to the factor in question to those not exposed. The epidemiologist then uses statistical methods and reasoning to allow her to draw a biological inference between the factor being studied and the disease's etiology.[13]

One difficulty with epidemiologic studies is that often several factors can cause the same disease. Birth defects are known to be caused by mercury, nicotine, alcohol, radiation, and viruses, among other factors. When epidemiologists compare the birth defect rates for women who took Bendectin during pregnancy against

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[12] *See also Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir.1987) (affirming the exclusion of expert testimony under Fed.R.Evid. 403 and 703 after questioning the expert's reasoning and lack of peer review).

[13] *See* A. Lilienfeld & D. Lilienfeld, Foundations of Epidemiology 3 (2d Ed.1980).

those who did not take Bendectin during pregnancy, there is a chance that the distribution of the other causal factors may not be even between the two groups. Usually, (sic) the larger the size of the sample, the more likely that random chance will lead to an even distribution of these factors among the two comparison groups, unless there is a dependence between some of the other factors and the factor being studied. For example, there would be a dependence between variables if women who took Bendectin during pregnancy were more or less likely to smoke than women who did not take Bendectin. Another source of error in epidemiological studies is selective recall – i.e., women who have children with birth defects may be more likely to remember taking Bendectin during pregnancy than those women with normal children. Fortunately, we do not have to resolve any of the above questions, since the studies presented to us incorporate the possibility of these factors by use of a *confidence interval.* The purpose of our mentioning these sources of error is to provide some background regarding the importance of confidence intervals.

In this case, the parties described the results of epidemiologic studies in terms of two numbers: a relative risk and a confidence interval. The relative risk is a number which describes the increased or decreased incidence of the disease in question in the population exposed to the factor as compared to the control population not exposed to the factor. In this case, the relative risk describes the increased or decreased incidence of birth defects in the group of women who took Bendectin versus women who did not take Bendectin. A relative risk of 1.0 means that the incidence of birth defects in the

two groups were the same. A relative risk greater than 1.0 means that there were more birth defects in the group of women who took Bendectin.

Just because an epidemiological study concludes that a relative risk is greater than 1.0 does not establish that the factor caused the disease. If the confidence interval is so great that it includes the number 1.0, then the study will be said to show no statistically significant association between the factor and the disease. For example, if a study concluded that the relative risk for Bendectin was 1.30, which is consistent with a 30% elevated risk of harm, but the confidence interval was from 0.95 to 1.82, then no statistically significant conclusions could be drawn from this study because the relative risk, when adjusted by the confidence interval, includes 1.0. Again, it is important to remember that the confidence interval attempts to express mathematically the magnitude of possible error, due to the above mentioned sources as well as others, and therefore a study with a relative risk of greater than 1.0 must always be considered in light of its confidence interval before one can draw conclusions from it.

The Brocks relied on a reanalysis conducted by Dr. Jay Glasser of the previously conducted Heinonen study. The Heinonen study, which was conducted by Professor O.P. Heinonen under the auspices of the U.S. National Institute of Neurological and Communicative Disorders, was based on over 50,000 pregnancy records collected in the United States. Dr. Heinonen, in analyzing these records, found that approximately 1,000 women had taken Bendectin during the first four months of their

pregnancies. 63 of those women had infants with malformations as opposed to 3,200 out of 49,000 who had not taken Bendectin. This yielded a relative risk of 0.97 with confidence limits from 0.75 to 1.26. Therefore, this study does not support the proposition that Bendectin causes birth defects.

The Heinonen study considered as birth defects all malformations, of which limb reduction defects of the type experienced by Rachel Brock are a subset. Dr. Glasser's reanalysis of the data used in the Heinonen study only considered limb reduction defects. That study found a relative risk of 1.49. However, Dr. Glasser admits that the confidence interval was from 0.17 to 3; this renders the study statistically insignificant. The plaintiffs did not offer one statistically significant (one whose confidence interval did not include 1.0) study that concludes that Bendectin is a human teratogen. No published epidemiological study has found a statistically significant increased risk between exposure to Bendectin and birth defects. One of Plaintiff's experts, Dr. Snodgrass, conceded that he was not aware of any such studies. Transcript at 198-99. Nor have any such studies been presented to the other two federal appeals courts which have considered this matter.[14]

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[14] *See Richardson by Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 831 (D.C.Cir.1988) ("Dr. Done [plaintiff's expert] further admitted that no one who has published work on Bendectin has concluded that there is a statistically significant association between Bendectin and limb reduction defects of the type at issue in this case."); *Lynch v. Merrell National Laboratories*, 830 F.2d 1190, 1194 (1st Cir.1987) ("On the basis of the

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Although we find Dr. Glasser's results inconclusive due to the fact that the confidence intervals include 1.0, we further note that Dr. Glasser has not published his study or conclusions for the purposes of peer review. While we do not hold that this failure, in and of itself, renders his conclusions inadmissible, courts must nonetheless be especially skeptical of medical and other scientific evidence that has not been subjected to thorough peer review. Clearly, "the examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine." *Richardson*, 857 F.2d at 831, n. 55 (quoting *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985).[15]

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epidemiological evidence to date, Bendectin is as likely as aspirin to cause limb reduction. . . . [W]orld wide scientific investigations of Bendectin have produced no evidence establishing that Bendectin causes limb reduction, and in which the irrelevance of Bendectin to the incidence of limb defects has been demonstrated.").

[15] In Richardson, the plaintiffs below submitted a reanalysis of data performed by Dr. Done. In holding this study to be inconclusive, the court prominently noted that Dr. Done had not published his findings nor had he submitted them for peer review. 857 F.2d at 831. Similarly, in Lynch, the plaintiffs presented the opinion of Dr. Swan, who based her opinion on a reanalysis of data collected by the Metropolitan Atlanta Congenital Defects Program. The court, after noting some serious methodological problems with the study, went on to say that:

> Swan's study has never been referred or published in a scientific journal or elswhere. (sic) We are informed of it only by the defendant's excerpts. On the basis of what we have, it could not form the

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We find, in this case, the lack of conclusive epidemiological proof to be fatal to the Brock's case. While we do not hold that epidemiologic proof is a necessary element in all toxic tort cases, it is certainly a very important element. This is especially true when the only other evidence is in the form of animal studies of questionable applicability to humans. We are not the first court to emphasize the importance of epidemiologic analysis. For instance, in *Heyman v. United States*, 506 F.Supp. 1145 (S.D.Fl.1981), which was one of the "swine flu" cases, the plaintiff had contracted Guillan-Barre Syndrome, allegedly caused by a swine flu innoculation (sic) under the National Swine Flu Immunization Program. In dismissing plaintiff's action for failure to prove that the swine flu vaccine caused her illness, the court held that "[g]iven the general inability of a physician to make accurate predictions of causation without at least some reference to epidemiological studies, plaintiff's position that her illness was caused by the swine flu shot amounts to nothing more than speculation." *Id.* at 1149.

The Brocks have also introduced animal studies in order to prove that Bendectin is a teratogen.

This circuit has previously realized the very limited usefulness of animal studies when confronted with questions of toxicity. In *Gulf South Insulation v. U.S. Consumer Product Safety Comm.*, 701 F.2d 1137 (5th Cir.1983), we

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foundation for an expert opinion challenging the scientific consensus and making the issue of causation a factual question to be decided by the jury.

Lynch, 830 F.2d at 1195.

vacated a urea-formaldehyde ban on foam insulation promulgated by the Consumer Product Safety Commission ("CPSC"). The CPSC, which is prohibited from promulgating a safety rule unless it has substantial evidence that a product poses an unreasonable risk of injury, banned urea-formaldehyde based on a high exposure rat study which showed a heightened risk of cancer. The court noted several methodological flaws which rendered the rat study inconclusive; specifically, the court focused on the small number of rats used in the study, the high (sometimes near-lethal) doses given, and the difficulty of extrapolating those results to humans. *Id.* at 1146.

We need not address at length the animal studies presented by plaintiffs below, except to note several of the more important studies and their methodological flaws. The plaintiffs presented an *in vitro* study conducted by Drs. Hassell and Horigan. This study used cells cut from the limbs of mice and chickens which were then exposed to various test compounds, including Bendectin. According to plaintiff's experts, limb bud cells which normally form in six days were reduced if those cells were exposed to Bendectin; these limb bud cells ultimately form the arms and legs. However, Dr. Hassell himself cautioned that the body may break down doxylamine, the active ingredient in Bendectin, into a metabolic product which may differ from the pure test compound. Thus, human limb bud cells in a fetus may not be exposed to doxylamine, but rather the metabolic product of doxylamine. Moreover, extrapolation of these findings to humans cannot be done without knowing the dosage level and the corresponding drug level in the bloodstream of the mother. Transcript at 674. Taking the

concept of metabolic products one step further, the plaintiff introduced the testimony of Drs. Snodgrass and Newman, who hypothesized that the human body breaks down doxylamine into less complex molecules called metabolites. These metabolites, some of which are negatively charged, are attracted to the relatively alkaline embryotic (sic) fluids, and ultimately bond with the cells in the embryo, producing tissue damage. Transcript at 629-30. However, both experts admitted that different species of animals metabolize chemicals differently, and that there are no studies which show that doxylamine is broken down by humans into toxic metabolites. Transcript at 181. Thus, we must view the limb bud test as quite speculative.

Other plaintiffs' experts conducted animal tests and reanalyses of previously performed animal tests. Drs. Thiersch and Glauser both reanalyzed results of previous studies on animals. Both admitted that the results of their animal studies are difficult to extrapolate to humans. Dr. Thiersch admitted in his deposition that one must rely, in part, on epidemiological studies to determine whether a substance is toxic in humans. Similarly, Dr. Glauser admitted that the only way to tell whether a substance is teratogenic in humans is to look to the human experience.

Dr. McBride, another expert called by plaintiffs, conducted research in Australia, exposing white rabbits and marmosets to high doses of doxylamine – up to 500 times the normal human dose.[16] 13 of 18 of the rabbits died due to either the toxic effects of doxylamine or the improper

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[16] At trial, there was some question raised as to whether Dr. McBride had falsified the results of his study. One of Dr.

(Continued on following page)

insertion of gavage tubes which were used to administer the doxylamine to the rabbits. Of the marmosets, all four which were given high doses of doxylamine (500 times the human dosage) aborted their fetuses, and it was impossible to tell if those fetuses were malformed since the aborted fetus is generally eaten by the mother. Dr. McBride hypothesized that the abortions were the result of the teratogenic effect of doxylamine, rather than the high dosage. However, the fifth marmoset was given a lesser dose (100 times the human dosage), and two of the three fetuses later examined lacked a hind leg. On the basis of this, Dr. McBride concluded that doxylamine is a teratogen. He hypothesized that Bendectin, an anticholinergic drug, reduces the amount of acetylcholine, a neurotransmitter released by nerve cells, in the embryo. If the amount of acetylcholine in the embryo is diminished, the trophic effect on body growth is interfered with. Essentially, Dr. McBride speculated that the development of body tissue depends on the initial development of the nervous system. He cited another hypothesis, that of Professor Alexander Karczman, as supporting his theory of the anticholinergic action of doxylamine.

(Continued from previous page)

McBride's lab assistants during the experiments, Mr. Phillip Vardy, testified during the damages phase of trial that Dr. McBride's published results differed from the notes that Mr. Vardy kept during the experiments. The Brocks, in turn, have alleged that Mr. Vardy was improperly financially reimbursed by Merrell-Dow for his testimony, and that Mr. Vardy failed to disclose this financial arrangement when he was questioned about it. The Brocks filed a post appeal motion to supplement the record in regards to this issue, and that motion was denied. We need not address the merits of this argument, since we have held that, taken at face value, Dr. McBride's conclusions are too speculative to support causation in the absence of epidemiological support.

However, the theory regarding the effects of doxylamine on acetylcholine, the nervous system and, ultimately, tissue development is nothing more than unproven medical speculation lacking any sort of consensus. Assuredly, one day in the future, medical science may have a clearer understanding of the mechanics of tissue development in the fetus. However, that is not the case today, and speculation unconfirmed by epidemiologic proof cannot form the basis for causation in a court of law.

In light of the evidence presented, we are convinced that the Brocks did not present sufficient evidence regarding causation to allow a trier of fact to make a reasonable inference that Bendectin caused Rachel Brock's limb reduction defect. We expect that our decision here will have a precedential effect on other cases pending in this circuit which allege Bendectin as the cause of birth defects. Hopefully, our decision will have the effect of encouraging district judges faced with medical and epidemiologic proof in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and conclusiveness of studies presented by both sides. However, we do not wish this case to stand as a bar to future Bendectin cases in the event that new and conclusive studies emerge which would give a jury a firmer basis on which to determine the issue of causation.

Accordingly, the judgment below is REVERSED and RENDERED, and the court below will enter an order of dismissal.

Mr. & Mrs. Floyd BROCK, individually and as next friend of Rachel Brock, a minor, Plaintiffs-Appellees,

v.

MERRELL DOW PHARMACEUTICALS, INC., Defendant-Appellant.

No. 88-2311.

United States Court of Appeals, Fifth Circuit.

Aug. 15, 1989.

O.J. Weber, Mehaffey, Weber, Keigh & Gonsoulin, Beaumont, Tex., Robert M. Dato, Ramey, Flock, Hutchins, Jeffus, McClendon & Crawford, P.C., for defendants-appellants.

Thomas H. Bleakley, Detroit, Mich., W. James Kronzer, Richard Warren Mithoff, Houston, Tex., for plaintiffs-appellees.

Appeal from the United States District Court for the Eastern District of Texas, William M. Steger, Judge.

ON PETITION FOR REHEARING

Before GARZA, JOLLY, and JONES, Circuit Judges.

PER CURIAM:

Appellees have filed a petition for rehearing en banc with regard to our prior disposition of this case, *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 308 (5th Cir.1989). Treating that petition as a petition for panel rehearing, we hereby modify our prior panel opinion.

At 313, we stated that "[w]e find, in this case, the lack of conclusive epidemiological proof to be fatal to the Brocks' case." We hereby change that sentence to read

"[w]e find, in this case, the Brocks' failure to present statistically significant epidemiological proof that Bendectin causes limb reduction defects to be fatal to their case."

We also change the last two sentences of the second to last paragraph on 315, which read:

> Hopefully, our decision will have the effect of encouraging district judges faced with medical and epidemiologic proof in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and conclusiveness of studies presented by both sides. However, we do not wish this case to stand as a bar to future Bendectin cases in the event that new and conclusive studies emerge which would give a jury a firmer basis on which to determine the issue of causation.

These sentences should read as follows:

> Hopefully, our decision will have the effect of encouraging district judges faced with medical and epidemiologic proof in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and statistical significance of studies presented by both sides. However, we do not wish this case to stand as a bar to future Bendectin cases in the event that new and statistically significant studies emerge which would give a jury a firmer basis on which to determine the issue of causation.

With the exception of the above changes, the panel adheres to its prior opinion in this case.

Mr. and Mrs. Floyd BROCK, individually and as next friend of Rachel Brock, a minor, Plaintiffs-Appellees,

v.

MERRELL DOW PHARMACEUTICALS, INC., Defendant-Appellant.

No. 88-2311.

United States Court of Appeals, Fifth Circuit.

Sept. 8, 1989.

Robert M. Dato, Santa Monica, Cal., O.J. Weber, Mehaffey, Weber, Keigh & Gonsoulin, Beaumont, Tex., and Ramey, Flock, Hutchins, Jeffus, McClendon & Crawford, P.C., Tyler, Tex., for defendant-appellant.

Thomas H. Bleakley, Detroit, Mich., W. James Kronzer, and Richard Warren Mithoff, Houston, Tex., for plaintiffs-appellees.

Appeal from the United States District Court for the Eastern District of Texas, William M. Steger, District Judge.

(Opinion June 6, 5th Cir., 1989, 874 F.2d 307)

Before CLARK, Chief Judge, GEE, REAVLEY, POLITZ, KING, JOHNSON, WILLIAMS, GARWOOD, JOLLY, HIGGINBOTHAM, DAVIS, JONES, SMITH, and DUHE, Circuit Judges.

ON SUGGESTION FOR REHEARING EN BANC

PER CURIAM:

The judges in regular active service of this court having been polled at the request of one of them, and a majority of the judges having voted against granting

rehearing en banc in this case (Federal Rules of Appellate Procedure and Local Rule 35), the suggestion for Rehearing En Banc is DENIED.

REAVLEY, Circuit Judge, with whom POLITZ, KING, JOHNSON, WILLIAMS and HIGGINBOTHAM, Circuit Judges, join dissenting from the denial of rehearing en banc:

If the court, by refusing to rehear en banc, approves the panel's application of *Boeing Co. v. Shipman*, 411 F.2d 365 (5th Cir.1969), I wonder what is left in this circuit of the *Boeing* rule or, for that matter, the Seventh Amendment right to trial by jury.

Six highly qualified and experienced experts testified that bendectin is a human teratogen, i.e. capable of causing human birth defects. Three of them testified to the opinion that bendectin was a cause of Rachel Brock's deformation. Their opinions of causation were not the product of faulty syllogisms but were predicated upon medical study and research and upon their explanation of the process by which the doxylamine element in bendectin can interfere with the development of nerve cells in an embryo. The panel picks at details in the testimony lacking expert consensus, but its characterization of this voluminous expert proof as "speculation" could just as well doom virtually all expert testimony. The panel reaches its climax with the novel declaration that only epidemiological studies can prove causal relation between bendectin and birth defects, and it enters into the debate with Dr. Glasser on the statistical significance of the Heinonen study. In the absence of expert consensus must we now always await population studies before a jury verdict

may be based upon medical opinion? So says the panel, at least for bendectin cases. This, despite the testimony here that case reports and laboratory research reveal teratogens and that no epidemiological study has ever discovered a teratogen.

The panel tries to draw support from *Richardson by Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C.Cir. 1988), but that court ruled that the plaintiff's medical expert lacked an adequate basis, of the type reasonably relied upon by experts in his field, for his opinion, which left no support for the verdict. That record was a far cry from the one we are called upon to review here. Though it tinkers with bits of the extensive expert testimony in this record, our panel does not purport to hold that the foundation for the opinions of these experts fails to satisfy Federal Rule of Evidence 703.

We dissent.

PATRICK E. HIGGINBOTHAM, Circuit Judge, concurring in Circuit Judge REAVLEY's dissent:

I join Judge Reavley in dissenting from the refusal of the court to consider this case en banc. I do not dissent because I think that the panel reached the wrong conclusion – about that I am not sure. I prefer to examine this case en banc because the panel's opinion shies from a direct confrontation with one of the most vexing problems currently facing the federal courts – the role of experts.[1] This case raises important questions about the

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[1] I doubt that the drafters of the Federal Rules of Evidence foresaw the impact of their changes in the rules for expert

(Continued on following page)

role of experts in the federal courts including whether we should accept opinions of experts not based upon a generally accepted scientific principle and the more broadly stated concern that substantive principles such as tort law are not handling science issues in a rational manner.[2] We should confront them – and state the guiding principle, if we can.

A significant body of judicial and academic comment has expressed fear concerning these dangers. Several examples of such comments were collected by Barry Epstein and Marc Klein in an article for *Seton Hall Law Review*.[3] The authors found such concerns expressed as early as 1853 in the following language from a federal court opinion:

> [T]he experience of all concerned in the administration of justice tends to the conclusion that this species of evidence is less satisfactory than any other. . . .[W]here there is any room for a difference of opinion, experts, in about equal

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witnesses. The changes were seen as enhancing efficiency and adopting for the courtroom standards of reliance sufficient for the community in its daily affairs. The actual changes have cut more deeply and indeed, in many ways, have materially changed the dynamics of trial.

[2] This question has, of course, been debated in varying intensity since the 1923 decision of the District of Columbia Circuit Court of Appeals in *Frye v. United States*, 293 F.1013 (D.C.Cir.1923). Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv.L.Rev. 40 (1901).

[3] Epstein & Klein, *The Use and Abuse of Expert Testimony in Product Liability Actions*, 17 Seton Hall L.Rev. 656 (1987).

> numbers, will generally be found testifying on each side.[4]

Much more recently, the Attorney General's Tort Policy Working Group reported an "increasingly serious problem" of

> reliance by judges and juries on noncredible scientific or medical testimony, studies or opinions. It has become all too "common" for 'experts' or 'studies' on the fringes of or even well beyond the outer parameters of mainstream scientific or medical views to be presented to juries as valid evidence from which conclusions can be drawn. The use of such invalid scientific evidence (commonly referred to as 'junk science') has resulted in findings of causation which simply cannot be justified or understood from the standpoint of the current state of credible scientific and medical knowledge. Most importantly, this development has led to a deep and growing cynicism about the ability of tort law to deal with difficult scientific and medical concepts in a principled and rational way.[5]

It has been eighty-eight years since Judge Learned Hand identified two practical defects with a system depending on a conflict between expert witnesses in front of a lay jury. First, he wrote, "the expert becomes a hired champion of one side":

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[4] *Id.* at 660 n. 13 (quoting *Wilkinson v. Greely*, 29 F.Cas. 1259, 1262-63 (C.C.D.Mass.1853)).

[5] *Id.* at 656-57 (quoting Report of the Tort Policy Working Group on the Causes, Extent and Policy Implications of the Current Crisis in Insurance Availability and Affordability (February 1986)).

> Enough has been said elsewhere as to the natural bias of one called in such matters to represent a single side and liberally paid to defend it. Human nature is too weak for that. . . .

Second, Hand asserted, the conflict between opposing experts leaves the jury no rational basis for choosing between them:

> The trouble with all this is that it is setting the jury to decide, where doctors disagree. The whole object of the expert is to tell the jury, not facts, as we have seen, but general truths derived from his specialized experience. But how can the jury judge between two statements each founded upon an experience confessedly foreign in kind to their own? It is just because they are incompetent for such a task that the expert is necessary at all.

It strikes me that the issue in this case revolves around the admissibility of the expert testimony. Indeed, we ought to be wary of opinions of scientists expressed in court free of their traditional restraints of peer review and scientific consensus. *See In re Air Crash Disaster at New Orleans, Louisiana*, 795 F.2d 1230 (5th Cir.1986). Yet, while skepticism permeates its opinion, the panel does not seem to engage the question at this juncture. Rather, the panel chooses to accept the admissibility of the testimony and to quarrel with its effect. I share much of the panel's concern and might join them if I were confident of their focus. Yet, the translation of these concerns into administrable rules is absent. The concerns only manage to bubble to the surface and then not in a coherent way that fully discloses.

Regardless, the issues reach further than questions of correct application of the rules of evidence in a particular case. Surely, these questions are worthy of en banc consideration, particularly when we cannot today close our eyes to the rapidly increasing upward pressure of an expanding base of federal cases. This upward force, capped at the top by the full capacity of the Supreme Court, is generating serious proposals for changing the structure of the Courts of Appeals. We are obligated to use our resources as best we can to mitigate this pressure. This means that we must be more willing to utilize en banc procedures to tackle difficult problems by reducing intra-circuit and inter-circuit conflicts. It also means that we ought not leave this lion in the busy street of our trial courts and inevitably multiply the appellate workload.

Describing the issues in the language of efficiency and impact on the courts presents only a part, and not the most important part, of larger questions of fairness and judicial roles and our commitment to the jury system. Ultimately, it is no more than that we are obligated to state the law, certainly if we truly expect people to order their affairs by its measure. We are not doing that here. When we fail to explain, we must ask if it is because we cannot. I join Judge Reavley's wise caution.

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 88-2311

MR. & MRS. FLOYD BROCK, Individually and as Next Friend of Rachel Brock, A Minor,

Plaintiffs-Appellees,

versus

MERRELL DOW PHARMACEUTICALS, INC.,
Defendant-Appellant.

Appeal from the United States District Court for the Eastern District of Texas

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ON SUGGESTION FOR REHEARING EN BANC

(Opinion August 15, 5 Cir., 1989, ___F.2d___)

(SEPTEMBER 21, 1989)

Before GARZA, JOLLY and JONES, Circuit Judges.

PER CURIAM:

(✔) Treating the suggestion for rehearing en banc as a petition for panel rehearing, it is ordered that the petition for panel rehearing is DENIED. No member of the panel nor Judge in regular active service of this Court having requested that the Court be polled on rehearing en banc (Federal Rules of Appellate Procedure and Local Rule 35), the suggestion for Rehearing En Banc is DENIED.

( ) Treating the suggestion for rehearing en banc as a petition for panel rehearing, the petition for panel rehearing is DENIED. The judges in regular active service of this Court having been polled at the request of one of said judges and a majority of said judges not having voted in favor of it (Federal Rules of Appellate Procedure and Local Rule 35), the suggestion for Rehearing En Banc is DENIED.

ENTERED FOR THE COURT:

CLERK'S NOTE:
SEE FRAP AND LOCAL
RULES 41 FOR STAY OF THE
MANDATE

/s/ E. Grady Jolly
United States Circuit Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

MR. AND MRS. FLOYD BROCK, Individually and as Next Friend of RACHEL BROCK, a Minor	§	L-83-148-CA
Vs.	§	
MERRELL DOW PHARMACEUTICALS, INC.	§	

ORDER

(Filed March, 4, 1988)

On this day came on to be heard Defendant's Motion for Relief From Order Regarding Liability [FRCP 60(b)] and Motion for Mistrial and Motion for New Trial or, in the alternative, for Judgment Notwithstanding the Verdict and for Remittitur. After due consideration, the Court is of the opinion that these motions should be denied.

Plaintiffs filed this products liability action to recover for certain birth defects suffered by Rachel Brock as a result of her mother's ingestion of the drug Bendectin during pregnancy.

After separate trials on liability, causation and damages, the jury found for the Plaintiffs and awarded them actual and punitive damages.

The Defendant filed its Motion for Relief From Order Regarding Liability [FRCP 60(b)] and Motion for Mistrial after the liability phase of the trial. In addition, Defendant has now filed its motion for new trial or, in the alternative, for judgment notwithstanding the verdict,

and for remittitur. The Court will now address all of the points raised in Defendant's motions.

1. *Epidemiological Study and the Relationship Between Bendectin and Birth Defects in Humans*

Defendant asserts that Plaintiffs must come forward with some epidemiological evidence before they can be said to have proven that Bendectin causes birth defects in humans. The Defendant relies on *Gulf South Insulation v. United States Consumer Product Safety Commission*, 701 F.2d 1137 (5th Cir. 1983) and *Perry v. United States*, 755 F.2d 888 (11th Cir. 1985) for its proposition. However, the Court believes that a more correct reading of these cases is that epidemiological studies are needed to prove *conclusively* that Bendectin caused the birth defects. All that is required in this action is evidence which will support a verdict based on the "more probable than not" standard. In the trial of this case, the jury heard numerous hours of expert testimony from the Plaintiffs' witnesses. Several experts stated that in their opinion Bendectin was capable of causing human birth defects. For this reason, the Court is of the opinion that there is ample evidence to sustain the causation finding of the jury.

2. *Drug Warnings and "Unisom"*

Defendant objects to the introduction of warning labels accompanying the drug "Unisom." In essence, Defendant believes that this evidence was not relevant to the issue of causation. Furthermore, even if there were some probative value to the evidence, it should have been excluded under Fed. R. Evid. 403.

Unisom is a sedative which contains Doxylamine, a component of Bendectin. The warning label accompanying Unisom was introduced in the cross examination of Dr. James Newberne, an employee of Merrell Dow Research Institute. Doctor Newberne is employed by Merrell Dow as the Director of Drug Safety Assessment and as Vice President for Regulatory Affairs. As a result, he was questioned about the Defendant's conduct in the marketing of Bendectin.

After reviewing the record, the Court is of the opinion that Unisom and its accompanying warning labels were primarily used to impeach and contradict Doctor Newberne's testimony. Therefore, the Court is not convinced that error was committed in allowing this evidence into the record.

3. *Compensatory Damages and Future Medical Expenses*

Defendant requests that the Court enter a remittitur in the amount of $20,000.00 against the award to Mr. and Mrs. Brock for future medical expenses. Defendant asserts the amount is improper because it is unsupported by the evidence.

Defendant argues that future medical expenses should not be awarded because Plaintiffs failed to produce competent testimony as to the cost of future medical service. In Texas, the jury may make its award of future medical expenses "based upon the nature of the injuries, the medical care rendered before the trial, and the condition of the injured party." *Johnson v. Michelin Tire Corporation*, 812 F.2d 200, 210 (5th Cir. 1987); *City of Houston v. Moore*, 389 S.W.2d 545 (Tex. Civ. App. – Houston 1985,

writ ref'd. n.r.e.). Therefore, the Plaintiffs are not required to establish an exact dollar amount.

In addition, Defendant argues that Plaintiffs failed to prove that future medical expenses would be necessary and reasonable. However, the plaintiff is only required to show a reasonable probability that future medical expenses will be necessary. *Powell v. Underbrink*, 499 S.W.2d 206 (Tex. Civ. App. – San Antonio, 1973, writ ref'd n.r.e.).

Dr. Barry L. Bowser testified that there was a reasonable probability that reconstructive breast surgery on Rachel Brock may be necessary or desirable in the future. Also, although he would not recommend it, Doctor Bowser indicated that surgery on Rachel's left hand to correct the deformities would be plausible and should be Rachel's decision later on. Therefore, the Court is not convinced there is an absolute absence of evidence to support the jury's award of future medical expenses. See *Irvan v. Frozen Food Exp., Inc.*, 809 F.2d 1165 (5th Cir. 1987).

4. *Punitive Damages and FDA Regulation or Any Reprehensible Conduct*

Defendant contends that punitive damages should not have been awarded and requests the Court to set aside the award of punitive damages or to order a new trial. In essence, Defendant asserts there is no evidence to support a jury finding of gross negligence.

Under Texas law, a party is guilty of gross negligence when it acts with "that entire want of care which would raise the belief that the act or omission complained of

was the result of a conscious indifference to the rights or welfare of the person or persons to be affected by it." *Burk Royalty Co. v. Walls*, 616 S.W.2d 911, 920 (Tex. 1981). In addition, the Plaintiff must show that "the defendant knew about the peril, but [his] acts or omissions demonstrated that he didn't care." *Burk Royalty Co.* at 922.

The plaintiff may introduce direct evidence to prove gross negligence. However, "a plaintiff may objectively prove a defendant's gross negligence by proving that under the surrounding circumstances a reasonable person would have realized that his conduct created an extreme degree of risk to the safety of others." *Williams v. Steves Industries, Inc*, 699 S.W.2d 570, 573 (Tex. 1985).

In the damage phase of the trial, Plaintiffs introduced several expert witnesses who testified that Defendant's conduct in the marketing of Bendectin was either wanton or in willful disregard for the safety of unborn children.[1] In response, the Defendant through its witnesses vigorously defended its actions in marketing Bendectin.[2] Nevertheless, the jury found that Merrell Dow's conduct was grossly negligent or wantonly done.

In order for the Court to grant a new trial or strike the award of punitive damage, there must be an "absolute absence of evidence to support the jury's verdict." *Irvan v. Frozen Food Express, Inc.*, 809 F.2d 1165, 1166 (5th

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[1] Dr. Elizabeth Hillman and Dr. Alan Done testified that Merrell Dow's conduct was grossly negligent.

[2] Merrell Dow called Dr. James Newberne, Chuck Fisher and Dr. Mark Hoekenga to rebut Plaintiffs' evidence of gross negligence.

Cir. 1987). This Court is not convinced that there is an absolute absence of evidence on the Defendant's gross negligence. Therefore, the jury's finding of gross negligence and award of punitive damages will stand.

5. *Dr. William McBride and Scientific Fraud*

At the close of the liability phase of this action, Defendant filed its motion for relief from order regarding liability [F.R.C.P. 60(b)] a motion for mistrial based on the expert testimony of Dr. William McBride. In addition, the Defendant raises the alleged scientific fraud issue surrounding McBride in its motion for new trial, or, in the alternative, for judgment notwithstanding the verdict and for remittitur.

Defendant first asserts that relief should be granted under Fed. R. Civ. Pro. 60(b)(2) – newly discovered evidence. In order to prevail, the defendant must show: (1) the evidence was discovered following the trials; (2) it used due diligence to discover the evidence at the time of trial; (3) the evidence is not merely cumulative or impeaching; (4) it is material; and, (5) a new trial in which the evidence was introduced would probably produce a different result. *Chilson v. Metropolitan Transit Authority*, 796 F.2d 69 (5th Cir. 1986).

Merrell contends that it first learned of *public* accusations of scientific fraud by Doctor McBride after he testified in the liability phase of the trial. However, the Defendant admits in its Memorandum of Law in Support of Defendant's Motion for New Trial that Merrell Dow knew of accusations of fraud by Doctor McBride as early as 1984, from Mr. Phil Vardy, a former associate of Doctor

McBride. Further, Merrell admits that it agreed not to disclose this information without prior consent of Mr. Vardy.

Merrell now wishes to come, after an expensive and time consuming trial, and assert that it should not face the consequences of this agreement. Instead, Merrell wishes to take the position that until this evidence became part of the "public record", it did not exist and Merrell should not be charged with knowledge of it. Regardless of the "elaborate international procedure to obtain Mr. Vardy's consent and another likely court battle in Australia with Dr. McBride", this Court is of the opinion that Defendant failed to use due diligence in obtaining the necessary evidence to support accusations of fraud by Doctor McBride before he testified. In addition, the Court finds that the evidence was discovered before trial and is merely impeachment evidence. Therefore, Defendant's request for relief under 60(b)(2) will be denied.

Defendant next asserts that relief should be granted under Fed. R. Civ. Pro. 60(b)(3) – fraud, misrepresentation, or other misconduct of an adverse party. To prevail on its 60(b)(3) motion for relief, defendant must prove that an adverse party has obtained a verdict through fraud, misrepresentation or other misconduct. *Saenz v. Kennedy,,* 178 F.2d 417 (5th Cir. 1949). In addition, defendant must show that it was prevented from fully and fairly presenting his case or defense. *Rozier v. Ford Motor Co.*, 573 F.2d 1332 (5th Cir. 1978).

The Court is of the opinion that Defendant has not proven by clear and convincing evidence that a fraud was

committed on the Court. At most, Defendant raised a fact question through the rebuttal testimony of Doctor Vardy. The jury properly weighed the testimony and found for the Plaintiffs. Finally, any argument by Merrell that it was prevented from presenting Doctor Vardy earlier is meritless since Merrell knew of his accusations of fraud three years before trial. Therefore, Defendant's motion for relief under 60(b)(3) will be denied.

Finally, Defendant requests that the Court invoke Fed. R. Civ. Pro. 60(b)(6) to grant relief from the operation of the judgment. After review of the record, the Court is of the opinion that this motion will be denied. It is, therefore,

ORDERED that Defendant's Motion for Relief from Order Regarding Liability [FRCP 60(b)] and Motion for Mistrial and Motion for New Trial or, in the alternative, for Judgment Notwithstanding the Verdict and for Remittitur is hereby, in all respects, DENIED.

SIGNED this 4th day of March, 1988.

/s/ William M. Steger
UNITED STATES DISTRICT JUDGE

Supreme Court, U.S.
FILED
FEB 21 1990
JOSEPH F. SPANIOL, JR.
CLERK

No. 89-1189

In the Supreme Court of the United States

October Term, 1989

MR. AND MRS. FLOYD BROCK, individually and as next friend of RACHEL BROCK, a minor,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS INC.,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Should certiorari be granted where the decision below is in accord with that of the other federal circuits, holding that plaintiffs' evidence does not create a jury issue as to whether Bendectin causes human birth defects?

CORPORATE AFFILIATIONS OF RESPONDENT

Respondent Merrell Dow Pharmaceuticals Inc. is a wholly owned subsidiary of Marion Merrell Dow Inc., which is approximately 2/3 owned by The Dow Chemical Company. Their subsidiaries and affiliates that have securities in the hands of the public are the following:

Alamo Land Company, Inc.; Arabian Chemical Company Limited; Compagnie des Services Dowell Schlumberger; Chief Shipping Company; Cromarty Petroleum Company Limited; Chimtrade; Transformadora de Etileno S.A.; Vorakim Kima Sanayi Ve Ticaret A.S.; Dowell Schlumberger Canada, Inc.; Fort Saskatchewan Ethylene Storage Limited Partnership; H-D Tech, Inc.; Wabiskaw Explorations Ltd.; Haeger and Kaessner Limited; Viopal S.A.; Scotdril Offshore Company; Dow Corning Corporation; Dowell Schlumberger Corporation; Dowell Schlumberger Incorporated; El Dorado Terminals Company; Joliet Marine Terminal Trust Estate; M.D. Kasei Limited; Funai Pharmaceuticals Company Ltd.; First Chemical Factoring S.p.a.; Laboratories Industriales Farmaceuticos Ecuatorianos (L.I.F.E.); MDP (Holdings) Ltd.; Fort Saskatchewan Ethylene Storage Corporation; Oronzio de Nora Technologies BV; Oronzio de Nora Technologies S.p.a.; Pacific Chemicals Berhad; Petroquimica-Dow S.A.; P.T. Pacific Chemicals Indonesia; Vorakim Kimya Sanayi VE Ticaret A.S.; Oronzio de Nora Technologies S.p.a.; Ulsan Pacific Chemical Company Ltd.; Dow Kakoh Kabushiki Kaisha; Family Com. e Ind. de Productos de Limpeza Ltda.; Oronzio de

Nora S.A., (Lugano); Pacific Chemicals (Pakistan) Ltd.; Pacific Eurosemences, S.A.; DCU/LB Trust; Chief Shipping Company; Metal Mark, Inc.; Zip Pak Incorporated; Gurit-Essex, A.G.; Pacific Cable Products Sendirian Berhad; The Cynara Company; Dow Elanco B.V.; Etoxilados del Plata S.A.

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No. 89-1189

In the Supreme Court of the United States

October Term, 1989

MR. AND MRS. FLOYD BROCK, individually and as next friend of RACHEL BROCK, a minor,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS INC.,

Respondent.

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

STATEMENT OF THE CASE

1. The Trial.

Petitioners (plaintiffs below) proceeded to trial on the theory that Bendectin, a widely prescribed morning sickness medication,[1] was the cause of plaintiff Rachel Brock's birth

[1] Benedectin was approved by the Food and Drug Administration (FDA) in 1956 as safe for the treatment of nausea and vomiting in pregnancy and has been used in over 30 million pregnaancies. Respondent voluntarily discontinued the marketing of Benedectin in 1983 as the result of costs associated with litigation. Significantly, Bendectin remains approved by the FDA. As detailed *infra*, no scientist in any peer-reviewed medical or

defect, an anomaly known as Poland's Syndrome.[2] Petitioners attempted to support their theory through the testimony of expert witnesses. Among these experts was Jay Glasser, who has a Ph.D. in experimental statistics (but not epidemiology[3]). Dr. Glasser reanalyzed the data of certain previously conducted epidemiological studies, none of which had concluded that Bendectin causes birth defects. The results of Dr. Glasser's reanalysis were not statistically significant (Transcript at 1306); nonetheless, he concluded it was more likely than not that Bendectin caused Rachel Brock's birth defect. Petitioners also presented the testimony of five other experts concerning various tests conducted on animals or animal cells with Bendectin, but these experts conceded that the results of these tests could not necessarily be extrapolated to the human population and that one must rely, at least in part, on epidemiological studies to determine whether a substance is toxic in humans. On the basis of this evidence, the jury awarded petitioners $190,000 in compensatory damages and $310,000 in punitive damages against respondent Merrell Dow Pharmaceuticals Inc. (Merrell Dow). The district court denied Merrell Dow's motions for directed verdict and for judgment notwithstanding the verdict.

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scientific journal, or in any text or reference work, has ever concluded that Bendectin causes birth defects.

[2]Poland's Syndrome was first identified in 1841, and has thus been known to have existed for over 100 years prior to the development of Bendectin.

[3]As noted by the Fifth Circuit in this case, "[e]pidemiology attempts to define a relationship between a disease and a factor suspected of causing it."

2. The Fifth Circuit's Reversal.

On appeal to the Fifth Circuit, the Court of Appeals observed that, when faced with difficult medical questions of causation, "courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve disputes before them." (App. 7; 874 F.2d at 310.) After such an evaluation, the Court of Appeals concluded that petitioners "did not present sufficient evidence regarding causation to allow a trier of fact to make a reasonable inference that Bendectin caused Rachel Brock's limb reduction defect." (App. 20; 874 F.2d at 315.) The analysis of petitioners' evidence consisted of the following:

a. The Epidemiological Studies

As the Fifth Circuit observed, no published epidemiological study has found a statistically significant increased risk between exposure to Bendectin and birth defects in general, or limb reduction defects in particular. (App. 14; 874 F.2d at 312.) There have been approximately 40 such studies, making Bendectin one of the most studied drugs used in pregnancy. Although these studies vary somewhat in both size and methodology, the conclusions are the same: No statistically significant increased risk of limb reduction birth defects has been shown. (Transcript at 1016.) Significantly, after reviewing these studies and others, the FDA concluded in 1980 that there was no evidence that Bendectin caused birth defects. (Transcript at 864, 867.)

Petitioners attempted to overcome this wealth of epidemiological data through Dr. Glasser's "reanalysis" mentioned above. Even with such reanalysis, however, the Fifth Circuit observed that Dr. Glasser's results were not statistically significant. (App. 14; 874 F.2d at 312.) The court stated that no statistically significant studies were

presented to it or to the two other federal courts which have considered the matter. (*Ibid.*) Finally, the court noted that Dr. Glasser had not published his reanalysis for the purposes of peer review, and that courts must "be especially skeptical of medical or other scientific evidence that has not been subjected to thorough peer review." (App. 15; 874 F.2d at 313.) The court then stated: "While we do not hold that epidemiologic proof is a necessary element in all toxic tort cases, it is certainly a very important element. This is especially true when the only other evidence is in the form of animal studies of questionable applicability to humans." (App. 16; 874 F.2d at 313.)

b. The "In Vitro" Studies

In vitro studies are experiments performed on isolated tissue cells removed from living animals. Petitioners presented at trial the results of a study by Drs. Hassel and Horrigan which their experts claimed demonstrated the propensity of Bendectin to reduce the growth of "limb bud cells" taken from mice and chickens. However, Dr. Hassel himself cautioned against extrapolating the results of his study to humans because, among other things, the human body may break down Bendectin into less complex molecules which act differently than the pure test compound. (Transcript at 674.) Likewise, two of petitioners' experts theorized that the human body may metabolize Bendectin in such a way as to form toxic "metabolites," but both admitted that no studies confirm this theory. (Transcript at 181.) After reviewing this evidence, the Court of Appeals stated: "Thus, we must view the limb bud tests as quite speculative." (App. 18; 874 F.2d at 314.)

c. The Animal Studies

Petitioners' experts presented reanalyses of previously conducted animal tests and one original test that they claimed

supported their theory that Bendectin causes birth defects. There were a number of methodological flaws in this evidence, but notwithstanding these flaws, all three of petitioners'experts on this subject admitted that one must look to the human population—i.e., epidemiology—to tell whether a substance is toxic to humans.[4] Reviewing this evidence, the Court of Appeals found that it was speculative, and that "speculation unconfirmed by epidemiologic proof cannot form the basis for causation in a court of law." (App. 20; 874 F.2d at 315.) Since not one of the many epidemiological studies has shown a statistically significant association between the ingestion of Bendectin and limb reduction birth defects, the Court of Appeals reversed and rendered judgment in favor of Merrell Dow. The court stated, however, that future Bendectin cases would not be barred if new studies emerged that supported the opinions of plaintiffs' experts. (App. 20; 874 F.2d at 315.)

3. The Petition For Rehearing and for Rehearing En Banc.

In response to a petition for rehearing, the panel rendering the original opinion modified its decision by emphasizing that petitioners lacked "statistically significant" epidemiological studies rather than "conclusive" studies. (App. 21-22; 884 F.2d 166.) In response to petitioners' suggestion for rehearing en banc, the Court of Appeals voted 8-6 to deny the suggestion. Circuit Judge Reavley, writing for the six dissenters, attempted to distinguish the panel's opinion from *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110

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[4]The Court of Appeals in its opinion stated that Drs. Thiersch and Glauser conceded this point, which they did; respondent further notes that petitioners' other animal expert, Dr. McBride, made a similar concession. (Transcript at 432.)

S.Ct. 218 (1989). According to Judge Reavley, the *Richardson* court's conclusion that plaintiffs did not present a jury question as to whether Bendectin causes birth defects was based upon a finding that plaintiff's expert lacked an adequate basis, reasonably relied upon by experts in the field, for his opinion. Judge Reavley then stated: "That record was a far cry from the one we are called upon to review here." (App. 25; 884 F.2d at 168.) However, as respondent had pointed out in its reply brief to the Court of Appeals, the evidence presented in *Brock* was virtually the same as that presented in *Richardson*.

REASONS WHY THE PETITION SHOULD BE DENIED

I.

THERE IS NO CONFLICT AMONG THE CIRCUITS.

A. The courts of appeals are as one in Bendectin cases.

This is one of many actions filed against respondent alleging that Bendectin was the cause of a plaintiff's birth defect. The various federal courts of appeals have uniformly awarded judgment in favor of Merrell Dow. This uniformity stems from an established fact: No published study has concluded that Bendectin causes birth defects in humans.

Cases involving Bendectin have been reviewed by the various courts of appeals in differing procedural postures. Some cases have proceeded to trial, resulting in jury verdicts in favor of Merrell Dow, which the appellate courts have affirmed. *In re Bendectin Litigation*, 857 F.2d 290 (6th Cir. 1988), *cert. denied sub nom.. Hoffman v. Merrell Dow Pharmaceuticals Inc.*, 109 S.Ct. 788 (1989) (affirming verdict in multidistrict litigation); *Wilson v. Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149 (10th Cir. 1990). In other cases the courts have ruled for defendant as a matter of law. In *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987), the First Circuit affirmed summary judgment in favor of Merrell, agreeing with the district court that plaintiffs' evidence was too speculative to support a verdict in their favor and that their experts' opinion lacked proper foundation. 830 F.2d at 1194-1197. The court specifically found that animal studies and tests involving chemicals similar to those in Bendectin "do not have the capability of proving causation in human beings in the

absence of confirmatory epidemiological data." 830 F.2d at 1194.

This Court has recently refused to review a decision of the District of Columbia Circuit affirming the grant to defendant of judgment notwithstanding the verdict. *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989). The *Richardson* court, using an analysis similar to that of the First Circuit in *Lynch*, held that the jury could not properly reject the "overwhelming body" of epidemiological evidence indicating that Bendectin does not cause birth defects. 857 F.2d at 830. The court noted the extensive studies, none of which concluded that Bendectin is teratogenic, and concluded:

> Uniquely to this case, the law now has the benefit of twenty years of scientific study, and the published results must be given their just due.

857 F.2d at 832.[5]

In the present case, the Fifth Circuit followed the lead of the *Lynch* and *Richardson* courts: it gave the published epidemiological studies their just due. Epidemiological studies are crucial because their focus is on the human population, rather than animals, and a reasonable jury cannot conclude that Bendectin is a teratogen when the epidemiological data is uniformly to the contrary.

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[5]In affirming a jury verdict for defendant, the Tenth Circuit also has thought it "particularly significant" that there was uncontradicted evidence "that of the approximately forty epidemiological studies of Bendectin, none has shown a statistically significant association between ingestion of the drug and incidence of birth defects generally or limb defects in particular." *Wilson v. Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149, _____ (10th Cir. 1990).

Petitioners seek to make much of the fact that in *Lynch* and *Richardson* it was held that plaintiffs had failed to sustain their burden of proof because the opinions of their experts were inadmissible under Rule 703 of the Federal Rules of Evidence, while here the Fifth Circuit panel reached the same conclusion based more upon a traditional "sufficiency of the evidence" analysis.[6] This is a distinction without a difference. The sufficiency of the evidence to create an issue for the jury and the adequacy of the foundation for an expert's opinion under Rule 703 are both questions of law for the court. Whether the court finds the foundation so lacking that it holds that the expert's opinion should not have been received or whether the court holds that the evidence, even if admissible, does not support the inference necessary to a plaintiff's case does not alter the result: the overwhelming scientific findings are such that no reasonable jury could find that Bendectin causes birth defects.

B. The non-Bendectin cases are decisively different.

The decision below is limited by its terms to Bendectin cases. The panel expects the decision to have "a precedential effect on other cases pending in this circuit which allege Bendectin as the cause of birth defects", though noting that it

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[6]The opinion below includes a Rule 703 type of analysis. For example, the opinion states that "courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them." (App. 7; 874 F.2d at 310.) Similarly, after observing that the D.C. Circuit in *Richardson* "affirmed its willingness to look behind the conclusions of experts," the court stated: "We too, have chosen to take the same approach as the *Richardson* court . . . ." (App. 10-11; 874 F.2d at 311.) Although it is reasonable to read *Brock* as employing a Rule 703 type analysis, such a reading is not essential here.

would not stand as a bar even in future Bendectin cases if new scientific studies suggest otherwise. (App. 20; 874 F.2d at 315.) Petitioners attempt to give the appearance of a conflict by pointing to other cases involving products other than Bendectin in which the scientific evidence was very different from what it is with regard to Bendectin. The most prominent of these is *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 241 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986), involving a spermicide called Ortho-Gynol. In that case, however, "[p]laintiffs presented several epidemiological studies that indicated an association between spermicide use and deleterious effects on the fetus."788 F.2d at 744. It is one thing, as in *Wells*, to allow the factfinder to choose when the scientific evidence is inconclusive. It would be something very different to allow the factfinder to draw an inference that is contradicted by all of the many epidemiological studies.

The thorough and conclusive nature of the studies conducted on Bendectin serves also to distinguish this case from the other non-Bendectin decisions cited by petitioners. A leading case among those is *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). *Ferebee*, which was heavily relied on by the Eleventh Circuit in the *Wells* case just discussed, was distinguished on this very ground by the court that had decided it, the District of Columbia Circuit, in *Richardson*.. As Judge Robinson put it:

> . . . *Ferebee* stands for the proposition that courts should be very reluctant to alter a jury's verdict when the causation issue is novel and "stand[s] at the frontier of current medical and epidemiological inquiry. . . .
>
> The case before us, however, is not like *Ferebee*. Indeed, we are at the other end of the

> spectrum, a great distance from the "frontier of current medical and epidemiologial inquiry." And far from a paucity of scientific information on the oft-asserted claim of causal relationship of Bendectin and birth defects, the drug has been extensively studied and a wealth of published epidemiological data has been amassed, none of which concluded that the drug is teratogenic.

857 F.2d at 832 (emphasis deleted).

Not one of the cases cited by petitioners involves a product that has been studied as extensively, and with such uniform results, as Bendectin. Comparing the present case to non-Bendectin cases cannot serve to create a conflict among the circuits where none exists.

II.

THE PETITION PRESENTS NO SEVENTH AMENDMENT OR *ERIE* ISSUE.

Petitioners—probably in common with all petitioners who come here to object that a lower court has taken away a jury verdict in their favor—claim that the Seventh Amendment has been violated. Doubtless they think that they are more likely to get this Court's attention with a claim of "an error of constitutional dimension" (Petition at 8) than if they describe it as what it is: a claim that, in their view, the lower court has erred in the way it applied well-settled rules about sufficiency of evidence to a highly particular factual situation.

The Seventh Amendment does not guarantee a jury determination of all issues of fact. It prohibits reexamination of a fact tried by a jury only "otherwise . . . than according to the rules of the common law." It is well settled that the district courts and the courts of appeals have both the power and the duty to direct a verdict, or to set aside a verdict if one

has been returned, if the evidence was not sufficient to make an issue for the jury. *Neely v. Martin K. Eby Construction Co.*, 386 U.S. 317 (1967); *Galloway v. United States*, 319 U.S. 372 (1943). The rules a court must apply in testing whether there was an issue for the jury to decide have been stated and restated and are well-understood. "No one disagrees with the rules but only as to their application in a particular case." Wright, *Federal Courts* 641 (4th ed. 1983).

The court below fully understood the rules. It stated them accurately, but it went on to note the difficulty in applying "general and abstract formulations" to "the concrete factual situation at hand." (App. 3-4; 874 F.2d at 308-309.) It was well aware of the need for it to distinguish between reasonable inferences, which are within the sphere of the jury, and the unreasonable inferences, which a jury cannot be allowed to draw. It recognized the wisdom of Dean Cooper's description of this task:

> It is commonplace that in large part the problem of defining the range of reasonable inference is dependent on the unique circumstances of each particular case. No self-applying rule can be offered for determining what inferences are reasonable.

Cooper, *Directions for Directed Verdicts: A Compass for Federal Courts*, 55 Minn.L.Rev. 903, 956 (1971) (quoted App. 4 n. 4; 874 F.2d at 309 n. 4).

It was that recognition that caused the court below to take as its compass cases involving Bendectin, rather than cases with very different records and different scientific evidence involving Ortho-Gynol and other products. That is also why the application of the familiar rules of sufficiency to

"the unique circumstances" of a particular case is not a task worthy of the limited time of this Court.

There is a sense, however, in which the Seventh Amendment is relevant here. It is at least in part because of the Seventh Amendment that there is nothing to petitioners' claim that the decision below is contrary to the doctrine stemming from *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). The Seventh Amendment defines, for federal courts, when an issue is for the jury and when it must be decided as a question of law by the court. There is no reason to think that the Texas rules on sufficiency of the evidence differ from those applied in the federal courts, but if they did, it is clear that the federal court would be obliged to follow the federal test, rather than the state test. "[S]tate laws cannot alter the essential character or function of a federal court." *Herron v. Southern Pacific Co.*, 283 U.S. 91, 94 (1931). In a federal action for personal injuries, if the evidence is insufficient to make a jury issue "and the question is one of law, the judge has the right and duty to direct a verdict for the defendant." 283 U.S. at 96. "[T]here is a strong federal policy against allowing state rules to disrupt the judge-jury relationship in the federal courts." *Byrd v. Blue Ridge Rural Electric Cooperative*, 356 U.S. 525, 538 (1958). See also 9 Wright & Miller, *Federal Practice and Procedure: Civil* § 2525 (1971).

Petitioners further assert that the *Erie* doctrine is threatened because the Fifth Circuit's opinion has "expressly reallocated" their burden of proof by requiring them "to prove the association between Bendectin and limb reduction defects to a degree of likelihood of at least ninety-five percent." (Petition at 18-19.) Such statements stem from petitioners' confusion between "statistical significance" and "preponderance of the evidence." Statistical significance, insofar as it relates to this case, emanates from the world of

epidemiology. When an epidemiologist arrives at a figure of "relative risk" (i.e., whether there is an association between exposure and outcome), that figure may or may not reflect the true relative risk in the total population. Therefore, using statistical methods, an epidemiologist uses "confidence intervals" and is able to state, with some degree of certainty (usually 95%), that the relative risk will fall somewhere between the two confidence intervals.[7] The use of such confidence intervals does not result, however, in altering the standard of proof for civil trials. Instead, such tests reflect the standard selected by science as the threshold level of reliability of epidemiological data. Thus, statistical significance is related to an altogether different aspect of civil litigation, not the standard of proof for juries but the standard of reliability for scientific tests.

The Court of Appeals did not depart from the traditional "preponderance of the evidence" test in this case, and thereby create some kind of new "federal common law." Rather, it simply held that petitioners' proof did not rise to the level of a preponderance: petitioners could not have the benefit of an inference that flies in the face of twenty years of scientific research.

CONCLUSION.

The decision below is in harmony with those of the other federal appellate courts that have addressed the issue. It

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[7]Using the Heinonen study cited by the Fifth Circuit in this case as an example, the relative risk was 0.97, with confidence intervals of 0.75 and 1.26. Professor Heinonen could thus state with 95% certainty that the actual relative risk for the total human population fell somewhere between 0.75 and 1.26. As the Court of Appeals observed, a relative risk of 1.0 means no association between exposure and outcome; further, if the confidence intervals include 1.0, the study is deemed to be not statistically significant. (App. 12-13; 874 F.2d at 312.)

correctly applies settled principles about sufficiency of the evidence to create a jury issue. The petition for certiorari should be denied.

Respectfully submitted,

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County of Los Angeles

I, the undersigned, say: I am and was at all times herein mentioned, a citizen of the United States and a resident of the County of Los Angeles, over the age of eighteen (18) years and not a party to the within action or proceeding; that my business address is 11333 Iowa Avenue, Los Angeles, California 90025; that on February 20, 1990, I served the within *Brief in Opposition to Petition for Writ of Certiorari* in said action or proceeding by depositing true copies thereof, enclosed in a sealed envelope with postage thereon fully prepaid, in the United States mail at Los Angeles, California, by Express Mail, addressed as follows:

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(Original signed)

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No. 89-1189

In The

Supreme Court of the United States

October Term, 1989

MR. AND MRS. FLOYD BROCK, INDIVIDUALLY AND AS NEXT FRIEND OF RACHEL BROCK,

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In The

Supreme Court of the United States

October Term, 1989

MR. AND MRS. FLOYD BROCK, INDIVIDUALLY AND AS NEXT FRIEND OF RACHEL BROCK,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

REPLY BRIEF OF PETITIONERS

The decision of the panel below presents an extraordinarily important question: may a federal court, in order to further its stated desire to provide drug manufacturers with greater predictability, explicitly reject the "traditional role of the jury" and effectively establish a substantive rule of federal common law requiring "statistically significant epidemiological proof" of causation in "mass toxic tort" cases? That is why six judges of the en banc court not only accused the panel of disregarding Fifth Circuit precedent, but "wonder[ed] what is left . . . of the Seventh Amendment right to trial by jury." App. 24.

Instead of attempting to explain why this extraordinarily important question is not worthy of review, Merrell pretends that it does not exist. According to Merrell, the panel below did nothing unusual – its decision conflicts with no other and presents no important federal question. As the express words of the panel and the vehement dissent of the six members of the en banc court demonstrate, however, nothing could be further from the truth.

Before addressing Merrell's legal arguments, however, we must say a few words about Merrell's primary argument – the factual assertion that forty uncontradicted epidemiological studies conclusively prove that Bendectin does not cause birth defects. To begin with, the assertion is utterly false. As the evidence in this case showed, highly qualified scientists disagree as to whether Bendectin causes birth defects. The epidemiological studies performed to date are both contradictory and inconclusive.[1]

Far more importantly, the assertion is irrelevant. The question presented by this case is not whether Bendectin causes birth defects but *who will decide* whether Bendectin

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[1] Contrary to Merrell's assertions, there are not 40 epidemiological studies of the relationship between Bendectin and birth defects. There are approximately 53, only six of which address limb reduction. Of those 53, approximately 15 establish a "statistically significant" link between Bendectin and birth defects. They were entered into evidence. The other 38 – including the six that address limb reduction – are inconclusive and only some of those were entered into evidence. Merrell's assertion that the epidemiological studies are uncontradicted and conclusive is totally unwarranted, as is its reliance on the FDA (which had no need to act once Merrell withdrew Bendectin from the market) in footnote 1 of its brief.

causes birth defects – the jury or the judge – when highly qualified experts disagree. We address Merrell's legal arguments below.

I. THIS CASE CONFLICTS EVEN WITH BENDECTIN CASES IN OTHER CIRCUITS.

Merrell first argues that this case presents no conflict because the courts are "as one in Bendectin cases" and the "non-Bendectin cases are decisively different." In fact, the panel's decision below is an unprecedented departure from uniform rulings in both Bendectin and non-Bendectin cases. What is "decisively different" is the panel's extraordinary conclusion that, even when six qualified experts testify that a particular toxic agent caused plaintiff's injuries, the jury cannot properly base a verdict on that testimony unless there is "statistically significant epidemiological proof" to support it.

Reading Merrell's brief in opposition, one would think that every plaintiff in a Bendectin case had lost and that every court to address the question had held that the question of causation was so clear that it could not go to the jury, even when supported by admissible expert testimony, because of the lack of "statistically significant epidemiological proof." In reality, however, as Merrell well knows, many Bendectin victims have succeeded in proving to juries, as the Brocks did here, that Bendectin caused their injuries. *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C.App. 1986), *on subsequent appeal*, 563 A.2d 330 (D.C.App. 1989), *cert. denied*, No. 89-961, ___ S.Ct. ___ (Feb. 20, 1990) (affirming plaintiff's verdict); *Lanzollotti v. Merrell Dow Pharmaceuticals, Inc.*, No. 82-0183

(E.D. Pa. July 9, 1986) (overruling Merrell's motion for directed verdict following mistrial due to hung jury); *Blum v. Merrell Dow Pharmaceuticals, Inc.*, 385 Pa.Super. 151, 560 A.2d 212 (1989) (ordering new trial following plaintiff's verdict because case tried to a jury of less than twelve); *Raynor v. Merrell Dow Pharmaceuticals, Inc.*, No. 83-3506 (D.D.C. 1987) (verdict returned in June of 1987, post-trial motions still pending); *Ealy v. Richardson-Merrell, Inc.*, No. 83-3504 (D.D.C. October 1, 1987) (overruling Merrell's motion for j.n.o.v. following plaintiff's verdict). In each of these cases the trial courts, having had an opportunity to view the evidence first-hand, held, as the district court did here, that there is more than sufficient evidence to support a finding in plaintiffs' favor. Indeed, in the District of Columbia, Bendectin victims have not only gotten their cases to a jury and won, but the appellate courts have fully upheld the jury's verdict, firmly ruling that the "statistically significant epidemiological proof" required by the panel below is not necessary. *Oxendine, supra*, 506 A.2d at 1110. Merrell, of course, does not mention any of these cases.

Equally important, even the cases that Merrell does mention directly conflict with the ruling of the panel below. Thus, in both *In re Bendectin Litigation*, 857 F.2d 290 (6th Cir. 1988), *cert. denied sub nom., Hoffman v. Merrell Dow Pharmaceuticals, Inc.*, 109 S.Ct. 788 (1989) and *Wilson v. Merrell Dow Pharmaceuticals, Inc.*, 893 F.2d 1149 (10th Cir. 1990), the courts upheld verdicts after the district court had necessarily ruled *that there was sufficient evidence to permit the jury to rule in plaintiffs' favor.* In *In re Bendectin Litigation*, the Sixth Circuit even expressly acknowledged that "the jury verdict following trial here

might have been for the plaintiffs instead of for the defendant." 857 F.2d at 325. Recently, federal district judges in the First, Sixth, and Tenth Circuits have reaffirmed that whether Bendectin causes birth defects is a question for the jury.[2] All of these decisions were issued after the panel's opinion in this case, and, significantly, two of them were issued by the judges who had presided over the trials in *In re Bendectin* and *Wilson*. Thus, *In re Bendectin* and *Wilson* cannot conceivably stand for the proposition that a reasonable jury could not find that Bendectin causes birth defects. As Judge Rubin stated, "A contrary finding is unjustifiable without a pronouncement in this circuit that, as a matter of law, epidemiological studies are the sole basis upon which an expert may reasonably rely when forming an opinion on a drug's teratogenicity."[3]

Similarly, *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987), and *Richardson by Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C.Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989) provide no support for the decision below. In the former, the plaintiff submitted virtually no evidence in opposition to the motion for summary judgment. Consequently, a district court in the First Circuit subsequently facing the causation issue in a

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[2] *Comeau v. Richardson-Merrell, Inc.*, No. 85-0996 (D.Mass. March 1, 1990); *In re: Bendectin Products Liability Litigation*, No. 84-0963-N (E.D.Mich. January 17, 1990); *Barton v. Richardson-Merrell, Inc.*, No. 85-C-28 (D.Utah February 2, 1990); *Wilson v. Merrell Dow Pharmaceuticals, Inc.*, No. 82-C-710-E (N.D.Okla. March 2, 1990). Copies of all unreported decisions have been docketed with the Clerk of this Court and provided to counsel for respondents.

[3] *In re: Bendectin Products Liability Litigation, supra* note 2, at 10.

Bendectin case has refused to follow *Lynch*.[4] In *Richardson*, the court held the plaintiff's evidence inadmissible under Fed.R.Evid. 703. Neither court held – indeed, except for the panel below, no court has ever held – that qualified and admissible expert testimony of causation simply cannot be credited absent "statistically significant epidemiological proof."

Attempting to explain away the panel's astounding departure from established law, Merrell argues that the ruling below is limited to Bendectin cases and that non-Bendectin cases are different. A simple reading of the opinion reveals, however, that the panel did not limit its decision to Bendectin cases; on the contrary, it perceived its ruling as a potential "solution" to the "problem" of "mass toxic torts" in general. At least one district court in the Fifth Circuit has already responded accordingly, and has ruled that the evidence presented by the plaintiff in a case involving neurological damage allegedly caused by the drug Accutane was insufficient as a matter of law to support a jury finding that the drug caused the damage.[5] Responding to the plaintiff's attempt to distinguish *Brock* as a case turning on the peculiar medical research relating to Bendectin, the court in that case observed that

> the *Brock* court cites and discusses cases involving the swine flu vaccine, a urea-formaldehyde [sic], paraquat and Agent Orange. This court is of the opinion that *Brock, supra*, is applicable to and controlling in the case before this court.[6]

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[4] *See Comeau, supra* note 2.

[5] *See Thomas v. Hoffman-La Roche, Inc.*, No. 86-19-D-D (N.D.Miss. November 14, 1989).

[6] *Thomas, supra* note 5 at 14-15.

For this reason, Merrell's attempt to distinguish *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741 (11th Cir. 1986), *cert. denied*, 479 U.S. 950 (1986), *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C.Cir. 1984), *cert. denied*, 469 U.S. 1062 (1984), and the other cases cited in our petition at 15-17, is unavailing. Merrell's essential argument is that those cases are different because there, the scientific evidence was "inconclusive" (brief of respondent at 10) and here, the scientific evidence is "thorough and conclusive." *Id.* The "conclusiveness" of the causation evidence is, of course, an argument that the jury, as well as the trial court, rejected below. As noted above, the truth is that, as even the panel below conceded, Bendectin's teratogenicity is a subject "upon which even our brightest medical minds disagree." App. 6. When that is the case, as every court before the panel below has held, the jury is to hear and resolve the dispute among the experts. Because the decision below directly and dangerously conflicts with these rulings, it requires review by this Court.

II. THE COURT OF APPEALS EXCEEDED ITS POWER TO REVIEW THE JURY'S FINDINGS OF FACT, AND ADOPTED A SUBSTANTIVE RULE OF LAW IN VIOLATION OF THE RULE OF *ERIE*.

Merrell next asserts that this case presents no important federal question because it simply involves the application of well established rules to particular facts. It is precisely because these rules are so well established, however, that this case is so important. The panel in this case was quite explicit in its unwillingness to follow them.

As Merrell notes in its brief at 12, the court below "fully understood the rules. It stated them accurately." That fact makes all the more astonishing the court's overt refusal to follow them. The court insisted that the problems posed by "mass toxic tort" cases in general required that the rules, i.e., the "traditional role of the jury," be reconsidered. Indeed, it admittedly substituted its "opinion" for that of the jury's. That is why the six en banc dissenters "wonder[ed] what is left . . . of the Seventh Amendment." App. 24.

Precisely because the panel believed that the current rules, as applied, did not provide sufficient predictability to drug manufacturers, it announced a new rule – effectively establishing a federal common law requirement of "statistically significant epidemiological proof" in "mass toxic tort" cases. Merrell does not challenge the Brocks' contention that such a requirement is unheard of in Texas tort law, but argues instead that the Brocks are complaining of the standard applied by the court of appeals for determining the sufficiency of the evidence to support the jury's findings. This response misrepresents the nature of the Brocks' complaint. The Brocks do not complain that the court of appeals improperly applied a federal standard to determine whether the Brocks' evidence presented a jury issue, but that the court developed a brand new substantive requirement for establishing a right to recover in toxic tort cases. In the panel's view, proof "by a preponderance of the evidence" is not enough – statistically significant epidemiological proof is required.[7] But

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[7] To say that the court's opinion does not establish a new substantive prerequisite to recovery, but merely advises what

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Texas courts have never intimated that such statistical proof is a prerequisite to recovery. Indeed, the idea that a plaintiff's right to recovery hinges on whether he can produce an epidemiological study that has a ninety-five percent chance of being correct, which the court of appeals required of the Brocks in this case, would be anathema to a Texas court. The panel's opinion thus directly contravenes the directives of the Tenth Amendment and of this Court in *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), and must be reexamined.

CONCLUSION

The jury in this case accepted the plaintiff's proof of causation and rejected Merrell's evidence that Bendectin is not a teratogen, as have other juries throughout the country. The court of appeals, motivated by policy concerns that it was unauthorized and unqualified to evaluate, disregarded the jury's factual finding. If principles of federalism and the right to trial by jury are to mean

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proof is necessary to establish the necessary degree of likelihood, begs the question. Under the same reasoning, a federal court could adjust the state-prescribed standard of care in a strict liability case by stating that unless the plaintiff proved that the manufacturer actually knew of the hazard, plaintiff cannot sufficiently show that the product is unreasonably dangerous to comport with federal sufficiency of the evidence standards. Such legerdemain does not validly relieve the federal courts of the responsibility to judge liability under state standards.

anything in toxic tort cases, this Court should review the decision of the court of appeals in this case.

Respectfully submitted,

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